EFFECTIVENESS OF FACILITATED TUCKING ON LEVEL OF PAIN AMONG PRETERM INFANTS UNDERGOING PAINFUL PROCEDURE AT SELECTED HOSPITALS, CHENNAI, 2015.

DISSERTATION SUBMITTED TO

THE TAMIL NADU DR.M.G.R.MEDICAL UNIVERSITY

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IN PARTIAL FULFILMENT OF REQUIREMENT FOR THE DEGREE OF

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Certified that this is the bonafide work of

Ms. RUBIN SELVARANI.G
Omayal Achi College of Nursing
No. 45, Ambattur Road
Puzhal, Chennai – 600 066

COLLEGE SEAL :

SIGNATURE :

Dr. (Ms.) S.KANCHANA
R.N., R.M., M.Sc.(N)., Ph.D., Post. Doc (Res).,
Principal & Research Director, ICCR,
Omayal Achi College of Nursing,
Puzhal, Chennai – 600 066, Tamil Nadu.

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Approved by the Research Committee in December 2014

PROFESSOR IN NURSING RESEARCH
Dr. (Ms.) S. KANCHANA _____
R.N., R.M., M.Sc.(N)., Ph.D., Post. Doc (Res).,
Principal & Research Director, ICCR,
Omayal Achi College of Nursing,
Puzhal, Chennai – 600 066, Tamil Nadu.

MEDICAL EXPERTS
Dr. A.ANURADHA _____
MBBS, MD
Consultant Pediatrician and Neonatologist,
Choolaimedu,
Chennai – 600 094, Tamil Nadu.

Dr. JAYASHEELA.K _____
MBBS, MD (Paed), DM (Neonatology)
Neonatologist,
Sir Ivan Stedeford Hospital,
Ambattur, Chennai – 600 053, Tamil Nadu.

CLINICAL SPECIALITY – HOD & RESEARCH GUIDE
Mrs. RUTHRANI PRINCELY.J _____
R.N., R.M., M.Sc.(N)., [Ph.D(N)].,
Child Health Nursing,
Omayal Achi College of Nursing,
Puzhal, Chennai – 600 066, Tamil Nadu.

DISSERTATION SUBMITTED TO

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LIST OF ABBREVIATIONS

AAP	-	American Academy of Paediatrics.
APGAR	-	Appearance, Pulse, Grimace, Activity, Respiration.
ANOVA	-	Analysis of Variance.
CINHAL	-	Cumulative Index to Nursing & Allied Health.
CNE	-	Continuing Nursing Education.
FLACC	-	Face, Legs, Activity, Cry, Consolability.
FTP	-	Facilitated Tucking by Parents.
IASP	-	International Association for the Study of Pain.
ICCR	-	International Centre for Collaborative Research.
KMC	-	Kangaroo Mother Care.
MEDLINE	-	Medical Literature Analysis and Retrieval System Online.
NFCS	-	Neonatal Facial Coding System.
NICU	-	Neonatal Intensive Care Unit.
NIPS	-	Neonatal Infant Pain Scale.
NMR	-	Neonatal Mortality Rate.
PASPI	-	Pain Assessment Scale for Preterm Infants.
PAT	-	Pain Assessment Tool.
PIPP	-	Premature Infant Pain Profile Scale.
RCT	-	Randomised Control Trail.
ROP	-	Retinopathy of Prematurity.
WHO	-	World Health Organization.

LIST OF SYMBOLS

=	-	Equals To
<	-	Less than
>	-	More than
%	-	Percentage
-	-	Minus
×	-	Multiplication
F	-	ANOVA
N	-	Total number of samples
n	-	Number of samples
p	-	Significance

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Effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai.

Abstract:

Aim and objective: To assess and compare the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure. **Methodology:** Quantitative approach, quasi experimental post-test only design was adopted to assess the effectiveness of facilitated tucking on level of pain among 60 preterm infants (30 in study and 30 in control group) undergoing painful procedure who fulfilled the inclusion and exclusion criteria at Amma Hospital, Choolaimedu & Sir Ivan Stedeford Hospital, Ambattur, Chennai. Non-probability purposive sampling was used to select the samples. Facilitated tucking was performed on the preterm infants during painful procedure and the level of pain was assessed after the procedure and interpreted using Premature Infant Pain Profile (PIPP) Scale. **Results:** The study findings revealed that the post test mean pain score of preterm infants undergoing painful procedure in the study group was 3.2 with standard deviation of 2.7 and post test mean pain score of preterm infants in control group was 8.3 with standard deviation of 4.8. The calculated 't' value (-5.051) indicated that there was high statistical significance in the post test mean pain score among the preterm infants undergoing painful procedure at $p<0.001$ level. **Conclusion:** The result revealed that facilitated tucking was effective in reducing pain during painful procedures and can be practiced as a part of routine nursing care of preterm infants during painful procedures.

Keywords: *Facilitated tucking, level of pain, preterm infants, PIPP scale, painful procedure*

INTRODUCTION

Preterm infants are born in an untimely manner from the intra-uterine environment before their anatomy and physiology are prepared to cope with the extra-uterine environment. They are typically hospitalized in a hostile environment of the Neonatal Intensive Care Unit (NICU) where they undergo numerous tissue-damaging procedures that are part of clinical care.

Preterm infants are subjected to various degrees of discomfort. They lose body heat more easily, faces troubles in feeding, underdeveloped organs suck which place them under various complications. Pain is an acute stress that can potentially lead to long-term complications. Preterm infants are more vulnerable to the effects of repeated painful insult, exposing them to possible short term as well as long-term developmental and psychological problems in later part of childhood.

A variety of nonpharmacologic pain relief techniques have been shown to effectively reduce pain from minor procedures in preterm infants. These include use of oral sucrose/glucose, breastfeeding, non-nutritive sucking, “kangaroo care” (skin-to-skin contact), facilitated tucking (holding the arms and legs in a flexed position), swaddling, and developmental care.

Facilitated tucking is one of the simplest, safe, non-pharmacological and cost effective technique, simulating the condition of being in uterus. This makes the preterm infant comfortable, more secure with controlled response. It facilitates self-regulation by decreasing the physiologic response like prolonged heart rate elevation that contributes to the disequilibrium associated with pain and stress. Facilitated tucking improves the emotional security and reduces the pain perception.

The investigator during her clinical experience identified that preterm infants experience pain and exhibits various physiological and behavioural response painful procedures. The investigator viewed that such painful expressions of the fragile preterm infants were not given much clinical importance rather pampered by unsterilized pacifiers, blind administration of sucrose solutions which also subject them to unnecessary complications. Hence the investigator had felt that facilitated tucking is a safe and secured non-pharmacological nursing intervention to reduce pain and prevent the complications of unattended painful response.

Objective

1. To assess and compare the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure in study and control group.
2. To associate the selected demographic variables with the post test mean pain score among preterm infants undergoing painful procedure in study and control group.

Null hypotheses

NH_1- There is no significant difference between the level of pain among preterm infant in study and control group at $p < 0.05$ level.

NH_2- There is no significant association of the selected demographic variables with the post test mean pain score in study and control group at $p < 0.05$ level.

METHODOLOGY

A quasi experimental post test only research design was adopted to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure. The independent variable of this study was facilitated tucking and the dependent variable was level of pain undergoing painful procedure. The study was conducted in the NICU of Amma Hospital, Choolaimedu & Sir Ivan Stedeford Hospital, Ambattur, Chennai. The study population includes preterm infants with 26-36 weeks of gestation undergoing painful procedures. The sample size consisted of 60 preterm infants (30 in study and 30 in control group) who fulfilled the inclusion and exclusion criteria were selected by non-probability purposive sampling technique. The tool used to assess the pain was PIPP scale which consisted of two parameters (Physiological indicator: heart rate, oxygen saturation level and Behavioural indicator: sleep/wake state, brow bulge, eye squeeze and nasolabial furrow)

In the beginning of intervention the investigator assessed the demographic variables from the medical records and monitors the hemodynamic status of the preterm infant using calibrated pulseoxymeter as the base line physiological indicator for duration of 15 seconds. The investigator performed thorough hand hygiene and wore on a sterile apron, cap and face mask as aseptic precautionary measures. The investigator performed warming of hands by rubbing the palm against palm to provide facilitated tucking to the preterm infant by using sense of touch, gently turned the infant to the lateral side and positioned the arms and legs flexed, to the middle of the trunk. The neonatal nursing staff performed the heel-prick procedure on the positioned preterm infant. The investigator retained the facilitated tucking position and observed the physiological indicator such as maximum heart rate and minimum oxygen saturation from the calibrated pulse oxymeter for duration of 30 seconds and the behavioural indicators such as asleep/ wake state, brow bulge, nasolabial furrow, eye squeeze were video recorded by the staff nurse for the same duration of 30 seconds simultaneously after the painful procedure. The preterm infants in the control group were allowed to undergo verbal pampering as hospital routine. The level of pain was assessed by using PIPP scale.

RESULTS AND DISCUSSION

The findings revealed that 27(90.0%) of the preterm infants experienced mild pain, 3(10.0%) experienced moderate pain and none of them experienced severe pain in the study group. Whereas 15(50.0%) of the preterm infants experienced mild pain, 8(26.7%) experienced moderate pain and 7(23.3%) experienced severe pain in the control group. The post-test mean pain score in study group was 3.26 with the standard deviation 2.74, whereas the mean pain score of post test level of pain in control group was 8.36, with the standard deviation. The calculated unpaired "t" test value t= -5.051 was found to be highly statistically significant at $p<0.001$ level. These values indicate that there was reduction in the level of pain among preterm infants who received the nursing intervention facilitated tucking than the preterm infants who were allowed to follow the hospital routine during the painful procedures. Hence the null hypothesis NH1 stated earlier that **"There is no significant difference between the level of pain among preterm infant in study and control group at p <0.05 level" was rejected.**

There was no association of the selected demographic variables with the post test mean score of pain among preterm infants undergoing painful procedure in the study group whereas the demographic variables such as type of feed before the painful procedure shows near significance, length of hospitalization and external stimuli before the painful procedure shows statistical significance in control group. Hence the null hypothesis NH_2 stated earlier that **"There is no significant association of the selected demographic variables with the post test mean pain score was accepted in study group and rejected for the selected demographic variables in the control group at p <0.05 level".**

CONCLUSION

The study was aimed to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure. The findings revealed that there was significant reduction in level of pain in the study group who received facilitated tucking during painful procedure than the preterm infants who underwent hospital routine (t= -5.051) at $p <0.001$ level. Thus the nursing intervention facilitated tucking can be utilized by the neonatal nursing professionals in their clinical practice to reduce the level of procedural pain in preterm infants at the NICU and Neonatal wards.

IMPLICATIONS

The pediatric nurses can adopt facilitated tucking as a routine preterm care practice to reduce pain during painful procedures. The pediatric nurse being a nurse educator can integrate the major study findings in the nursing curriculum at various levels to build up and train the students to assess the level of pain using the PIPP scale and to prevent the long-term consequences of repeated painful stimuli. The generalization of the study results can be made through further replication of the study in larger population on various other painful procedures.

CHAPTER 1

INTRODUCTION

INTRODUCTION

"Premature", "Preemie" or "Preterm" babies are the ones who are born before 37 completed weeks of gestation. They may look tiny and fragile but are never underestimated by their appearance. They start with their smaller foot prints thereafter achieving beautiful life with patience, love and tender care over a period of time.

Preterm babies are assumed to be smaller and sicker based on their gestational age regardless of their birth weight. Babies born between 34-36 weeks of gestation are known as "Near term" or "Late preterm" infants and babies born between 26 – 34 weeks of gestation are "Early preterm" infants, whereas babies born before 26 weeks of gestation are said to be "very preterm" or "Micro-preemies" (Wongs Essentials of Pediatric Nursing, 9th edition, 2013).

Preterm infants are born before they are prepared to leave the womb of their mothers, often exhibiting numerous health problems. These newborn have higher rates of disabilities and even death, contributing to major part of neonatal mortality rate (American Academy of Paediatrics 2010).

According to the World Health Organization (WHO) these tender newborn babies are made perfectly healthy thereafter birth and developed normally both in body and mind, with some form of specialized supportive medical care after birth under well-equipped intensive care unit and skilled professionals.

Neonatal Intensive Care Unit (NICU) is a complex setting dedicated to promote growth and well- being of preterm infants. The number of intensive care days depends on the severity and response of the infants to the quality of medical and softness of nursing care being provided to them. However the preterm infants are subjected to various pain throbbing diagnostic and therapeutic procedures as a part of life saving treatment.

Preterm infants are highly sensitive to pain that place them under the risk of neuromuscular impairment during their latter part of childhood. The long term effects are varied from neuro-anatomical, behavioural, emotional and learning disabilities.

A variety of non-pharmacological nursing interventions have shown to reduce procedural pain in preterm infants effectively.

1.1 BACKGROUND OF THE STUDY

Preterm infants are babies who are small, often sick, and require medical attention. Preterm infants have increased risk of complications as they are not fully equipped to deal with life in the extra uterine world. Their little bodies still have underdeveloped parts that include the lungs, digestive system, immune system and skin.

Globally 15 million babies are born preterm each year in the world, more than one in 10 births, are born too early, according to Born Too Soon: the Global Action Report on Preterm Birth, released by World Health Organisation in the year 2013. The report points out that India has the maximum number of births out of which 3,519,100 of them are preterm. About 15 million babies are born preterm each year; that is more than one in ten babies worldwide. 60% are of them are born in sub-Saharan Africa and South Asia.

Table 1.2.1 The top 10 countries with the largest number of preterm birth rate (WHO 2013)

S.No.	Countries	Number of preterm birth
1.	India	3, 519,100
2.	China	1,172,300
3.	Nigeria	7,73,600
4.	Pakistan	7,48,100
5.	Indonesia	6,75,700
6.	The United States of America	5,17,400
7.	Bangladesh	4,24,100
8.	The Philippines	3,48,900
9.	The Democratic Republic of the Congo	3,41,400
10.	Brazil	2,79,300

Source: Born Too Soon: The Global Action Report on Preterm Birth (WHO, 2013).

About 0.76 million neonates die every year in India, the highest for any country in the world. The Neonatal Mortality Rate (NMR) of the country did decline from 52 per 1000 live births in 1990 to 29 per 1000 live births in 2012. With the current neonatal mortality rate 70% of the major causes are because of preterm birth.

Prematurity is major cause of infant deaths. Many premature infants have medical, developmental, or behavioural problems that continue into childhood and are permanent. The more premature an infant and the smaller the birth weight, the greater the risk of complications. Improved medical and nursing techniques have increased the survival of premature infants.

Preterm infants possess variety of special needs that make their care differ from that of full-term infants, which is why they often begin their lives after delivery in a NICU. The NICU is designed to provide an atmosphere that limits stress to the infant and meets basic needs of warmth, nutrition, and protection to ensure proper growth and development.

Preterm babies are at risk of developing disabilities that affects their entire lives. They lose body heat more easily, placing them at risk of hypothermia. They have feeding trouble because they possess underdeveloped suck and swallow reflex. Term infants start breathing on their own when they are born, but preterm need to be resuscitated. Their immune systems are not yet fully developed, and they have a higher risk of dying if they get an infection. Preterm babies can also have brain injuries from a lack of oxygen. Bleeding or lack of oxygen to the brain can result in result in cerebral palsy, developmental delays and learning difficulties.

Preterm infants emerge soon from a safe uterine environment that places them in a noisy chaotic, stressful and painful environment as a part of life saving treatment in NICU. Researchers have reported that exposure of the preterm infant under intensive care environment, with its continuous life-saving and skin- procedures, cause pain and have many negative impacts on the developing infant.

Pain is an acute stress that leads to disequilibrium in the physical, physiological, emotional and behavioural parameters to various degree of severity. Preterm infants are unable to communicate pain verbally and hence are commonly unrecognized and left untreated.

In NICU, every preterm infant are exposed to a high number of painful procedures and interventions, of these 65 % of the procedures are performed without pre and/or post anaesthesia or analgesia. The immature peripheral and central nervous system of the preterm infant responds differently to pain making these neurologically immature infants susceptible to long-term effects of pain.

Heel prick is one of the most common procedures routinely performed in newborn worldwide. Infants born preterm will be repeatedly exposed to heel prick in a day as part of their care in NICU. This acute invasive painful procedure is performed to obtain blood for routine screening and to measure serum bilirubin and glucose. Many studies have demonstrated neonatal bio-behavioural reactivity during and after a single heel prick. Significant increase in facial action, motor movements and cry during that procedure provide evidence that preterm experience pain during heel prick procedure.

Lina Kurdahi Badr, et al. (2010) in a cross-sectional study assessed the pain responses of 72 preterm infants to a heel stick procedure using Premature Infant Pain Profile (PIPP) scale and found that sick premature infants were exposed to a variety of painful procedures and they manifest behavioural and physiological signs of pain in single procedure. Doesburg SM, et al. (2013) in a longitudinal cohort studied on preterm infants followed from birth to school-age, and examined association of neonatal pain with functional brain activity later in childhood and found that greater cumulative neonatal pain-related stress was associated with altered spontaneous oscillatory brain activity using magneto encephalography at 7 years of age and found that neonatal pain exposure was associated with resting brain function in children born extremely preterm at 24–28 weeks.

Health care providers must recognize, evaluate and use variety of pain relief techniques in preterm infants to resist against the potential for later complications. Every health care facility caring for preterm infants should implement an effective pain prevention program, which includes strategies for assessing pain routinely, minimizing the number of painful procedures, and effectively using nonpharmacologic interventions for the prevention of pain associated with routine minor procedures.

A variety of nonpharmacologic pain relief techniques have been shown to effectively reduce pain from minor procedures in preterm infants. These include use of oral sucrose/glucose, breastfeeding, non-nutritive sucking, "kangaroo care" (skin-to-skin contact), facilitated tucking (holding the arms and legs in a flexed position), swaddling, and developmental care, which include limiting environmental stimuli and lateral positioning. These measures have been shown to be useful in preterm and term neonates in reducing pain from a heel stick, venepuncture, and subcutaneous injections.

Facilitated tucking is one of the simplest non-pharmacological and cost effective techniques simulating the condition of being in uterus. This makes the infant comfortable, more secure with controlled response. It facilitates self-regulation by decreasing the physiologic response like prolonged heart rate elevation that contributes to the disequilibrium associated with pain and stress. Facilitated tucking improves the emotional security and reduces the pain perception.

Multiple researchers (Hill S, et al. 2010; Mona Alinejad Naeini, et al. 2012) studied the effects of facilitated tucking on 12 preterm infants between 25 to 34 weeks that are subjected to painful procedures using PIPP scores. The findings revealed that infants in the treatment group had no pain whereas infants in the control group had severe pain and suggested facilitated tucking during routine care events reduces the stress level of the preterm infants during procedural pain.

The investigator during her clinical experience identified the physiological and behavioural response of the preterm infants to various painful procedures. Such painful expressions of the fragile neonates were not given much clinical importance rather pampered by unsterilized pacifiers, blind administration of sucrose solutions. Hence the investigator had felt the need of simple, cost effective, non-pharmacological nursing intervention to reduce pain and underlying complications of unattended pain response.

1.2 SIGNIFICANCE AND NEED FOR THE STUDY

Premature infants possess immature physical and physiological systems than that of the full term infants. Due to their under-developed organ systems they face various health issues such as feeding problems, respiratory collapse, infections, and experience a deep sense of separation from their parents as they are cared under the special therapeutic environment, the NICU.

Pain is defined as an unpleasant sensory and emotional experience and preterm infants not only feel the pain, but also respond more intensively compared with term infants. The experience of pain is always subjective. Hence, verbalization of nociceptive sensation is the gold standard for assessment of pain. Since preterm infants cannot verbalize pain, the recognition and management of pain in preterm infants is still suboptimal in neonatal intensive care units.

International Association for the Study of Pain (IASP) in 2010 documented in the systematic review search that babies born at less than 32 weeks of gestation are exposed to number of painful procedures each day during the first few weeks of life, and in almost 80% no treatment for pain relief is offered. When exposed to prolonged pain, preterm infants respond with few body movements, facial expressions, increased heart rate, respiratory variability, and decreased oxygen consumption, which all are the suggestive mark of energy conservation. The consequences of repeated pain include altered pain sensitivity which may last into adolescence, permanent neuro-anatomical, behavioural, emotional and learning disabilities.

Multiple studies (Rouzan 2010; Lago p, et al. 2013) reported that preterm infants often have several sources of pain and discomfort as they face up to 400 painful procedures while they are being cared for in NICU. They found that most common painful procedures performed daily include heel lancing, venepuncture, endotracheal intubation, suctioning, lumbar puncture and Retinopathy Of prematurity (ROP) screening.

The International Evidenced Based Group for neonatal pain and the American Academy of Paediatrics (2010) recommended that all neonatal units must develop strategies to assess the painful responses during procedures, minimize the number of

minor painful procedure and to provide non-pharmacological pain relief for preterm infants during painful procedure.

The heel prick procedure, is performed in the plantar surface of the heel where punctured by a lancet or a needle to a depth of 2-3 mm, is the most common way of drawing blood from newborn infants. Although, the heel stick procedure is short in duration, it can affect behavioural and physiological responses such as facial expression, heart rate, respiratory rate, and oxygen saturation of the infants. The short-term effects may include feeding problems, parent-infant interaction dysfunction, and interruption of sleep wake cycles. Possible long-term effects of repeated heel sticks include impairments of neurodevelopment, learning, and memory

Researchers (Lago P, et al. 2013; Carl Denis Britto 2014; D. Cruz, A.M. Fernandes, C.R. Oliveira, 2015) had documented that frequent painful procedures were performed routinely and pain medication was administered only to severe forms of painful procedure whereas the other routinely performed painful procedures were left unattended and stayed suboptimal. Carl Denis Britto (2014) enforced the awareness about the intensity of pain, assessment of pain, and formulating pain-reduction protocols for clinical pain management among the health care professional.

A volume of evidence (Eva L., 2012; Pankaja S. Venkataraman, 2012; Balasubramanian Sundaram and Vijay Pratap Singh, 2013; Hamid Peyrovi, et al. 2013; Sibel Kucukoglu , 2015) assessed the intensity of pain among preterm infants using PIPP scores and studied the effectiveness of facilitated tucking during and after heel prick procedures. These researches support that facilitated tucking is an effective comfort measure in attenuating premature neonate's physiological and behavioural responses to minor pain. Liaw JJ, et al. (2012) compared the effectiveness of two non-pharmacological pain-relief strategies (non-nutritive sucking and facilitated tucking) with routine care during, and after heel prick procedures and found that both non-nutritive sucking and facilitated tucking effectively reduced pain scores more than routine care during heel-stick procedures.

The investigator through her clinical experience understood the physiology of pain in preterm infants during single heel prick procedures. These painful responses

remained neglected since preterm infants are unable to communicate their intensity of pain. The investigator recognized that a valid tool must be used to assess the pain of preterm infants and practicable pain relief nursing care can be performed during routinely performed procedures. The investigator adopted facilitated tucking as the comforting measure to reduce procedural pain that confines the preterm infant and also prevent the long term consequences of repeated painful stimuli.

1.3 STATEMENT OF THE PROBLEM

A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai.

1.4 OBJECTIVES

1. To assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure in study and control group.
2. To associate the selected demographic variables with the post test mean pain score among preterm infants undergoing painful procedure in study and control group.

1.5 OPERATIONAL DEFINITIONS

1.5.1 Effectiveness

Refers to the outcome of facilitated tucking on level of pain among preterm infants undergoing painful procedure which was assessed using Premature Infant Pain Profile (PIPP) Scale after the procedure.

1.5.2 Facilitated Tucking

Refers to the sense of touch performed by the investigator once during the painful procedure i.e., heel prick , on the preterm infant by gently positioning them laterally with their arms and legs flexed, to the midline of the trunk under strict aseptic technique.

1.5.3 Level of pain

Refers to the unpleasant sensation experienced by the preterm infant undergoing painful procedure which was assessed after the procedure through manual recording of

physiological indicators and video recording of the facial expressions for duration of 30 seconds and interpreted by using PIPP Scale.

1.5.4 Preterm infant undergoing painful procedure

Infants born between 26-36 weeks of gestation who undergo only heel stick procedure in the Neonatal Intensive Care Unit, at selected Hospitals.

1.6 ASSUMPTION

1. Facilitated tucking may have an effect on level of pain among preterm infants undergoing painful procedure.

1.7 NULL HYPOTHESES

NH_1- There is no significant difference between the level of pain among preterm infant in study and control group at $p < 0.05$ level.

NH_2- There is no significant association of the selected demographic variables with the post test mean pain score in study and control group at $p < 0.05$ level.

1.8 DELIMITATION

The study was limited to a period of four weeks.

1.9 CONCEPTUAL FRAMEWORK

Conceptual framework is made of concepts and proportions that state the relationship between the concepts relevant to the study. Conceptual framework provides a foundation to for see the occurrence of the phenomena. It helps the investigator to proceed with the research in an organized and orderly process by generating ideas for research.

Kathrine Arnold (Kolcaba) born in 1994, graduated with RN MSN from Frances Payne Bolton School of Nursing in 1987. Kolcaba's theory of comfort was first developed in the year 1990. In 2005 she published an article; Comfort Theory and its application to pediatric nursing. This article applies Comfort Theory to paediatrics, while explain the current approach to paediatrics as attempting to relieve discomfort. It is a middle-range theory for health practice, education, and research. This theory has the

potential to place comfort in the forefront of the healthcare. According to the model, comfort is an immediate desirable outcome of nursing care.

The conceptual framework adopted for this study was based on modified Kolcaba's theory of comfort. The theorist Katherine Kolcaba states that the patients may have various level of discomfort arising from various health changes and she identified that appropriate identification of the health care needs, intervening variables and comforting interventions would promote enhanced comfort (relief, ease and transcendence) that ultimately lead to the framing of the best practices and best policies at the health care institution. The present study was aimed to reduce the level of pain among preterm infants undergoing painful procedure using facilitated tucking as the comforting measure. The theorist states that best practices leads to better quality of life. The framework consists of four components: Health care needs, comforting intervention, enhanced comfort and institutional integrity.

- **Health care needs of the preterm infant**

The theorist defines health care needs as those needs identified by the patient and/or family in particular nursing practice settings. In this study the investigator identified that preterm infants experience varying degrees of pain during painful procedures and hence the level of pain was identified as the health care need of the preterm infant.

- **Comforting interventions**

According to this theory, comforting measures refers to the nursing intervention that is designed to address the special health care needs accomplished by relief, ease and transcendence. Relief refers to the specific need of the person; in this study, relief refers to the level of pain of the preterm infant. Ease refers to the comfort experienced by the person; in this study comfort is experienced by the preterm infant by facilitated tucking during the painful procedure. Transcendence is the phase where the preterm infants meet their health care needs; in this study transcendence is reduction in the level of pain experienced by the preterm infant during painful procedure. The proposed intervention is administered to the study group and the control was allowed to undergo the hospital routine (verbal pampering).

- **Enhanced comfort**

According to the comfort theory, the enhanced comfort is the immediate desirable outcome of the nursing care accomplished by relief, ease and transcendence. In this study, the outcome was assessed by the level of pain using PIPP scale.

Reinforcement – if there was reduction in the level of pain after providing facilitated tucking, the investigator recommended for reinforcement of the facilitated tucking as regular preterm pain relief measure.

Enhancement – if there was no reduction in the level of pain, the investigator insists on the reassessment of pain by PIPP scale and use of facilitated tucking as comfort measure.

- **Institutional integrity**

Institutional integrity includes the best practices and best policies which the institution frames as procedures and protocols for the overall use after collecting the evidences. In this study the investigator reported the finding of the study and facilitated tucking at Amma Hospital, Choolaimedu & Sir Ivan Stedeford Hospital, and Ambattur, Chennai.

The Medical Directors and the Neonatologist of both the Hospitals appreciated the findings of the study and willingly accepted to implement facilitated tucking as routine pain relief measure for preterm infants during painful procedures and also ensured to provide training for the neonatal staffs for performing facilitated tucking as a routine care of preterm undergoing painful procedure.

Thus the investigator had adopted Kolcaba theory of comfort in this study which served as a perfect guidance and structured layout in identifying the needs of the preterm infant and achieving the desirable outcome by means of nursing comfort measure. This also enabled the investigator to correlate various aspects of theory and implement into nursing practice and identify the effectiveness of facilitated tucking in reducing pain during routine painful procedure.

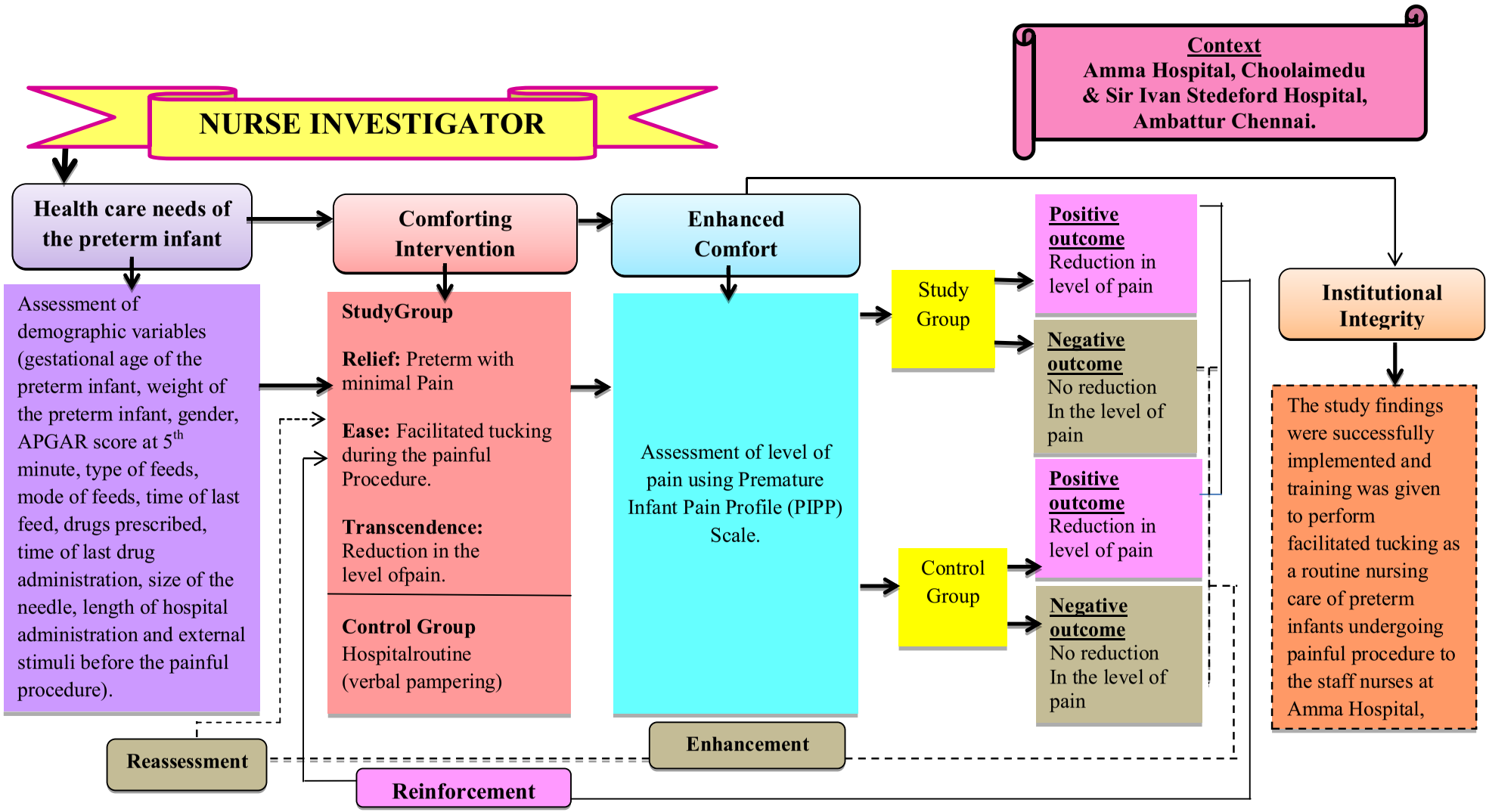


FIG 1.1 CONCEPTUAL FRAMEWORK BASED ONKOLCABA'S THEORY OF COMFORT, 2010

1.10 OUTLINE OF THE REPORT

Chapter 1: Deals with the background of the study, need for the study, statement of the problem, objectives, operational definitions, research hypothesis, assumptions, conceptual framework and delimitation of the study.

Chapter 2: Deals with review of literature.

Chapter 3: Presents the methodology of the study and plan for data analysis.

Chapter 4: Focuses on data analysis and data interpretation.

Chapter 5: Enumerates the discussion of the study

Chapter 6: Contains the summary, conclusions, implications, recommendations and limitations.

The study report ends with selected references and appendices.

CHAPTER 2

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Review of literature is a systematic and logical arrangement of information that is carefully selected from scientific writings. The ultimate purpose of a good review of literature is to find out the best available evidences from various updated sources and organize them scientifically within the framework of current research project.

This review of literature was done using the key words such as preterm infants, pain in preterm infants, assessment of pain in preterm infants, procedural pain, common painful procedures, heel lancing, effects of procedural pain, pain relief measures, pain alleviation techniques, non-pharmacological pain management, and facilitated tucking. This review was searched based on standard databases such as Cochrane library, Cumulative Index to Nursing & Allied Health (CINHAL), Google Scholar, Medical Literature Analysis and Retrieval System Online (MEDLINE), PubMed and other unpublished studies from dissertations. It includes cross-sectional surveys, crossover studies, cohort studies, longitudinal prospective studies systematic reviews, Randomized Controlled Trials (RCTs) and quasi-experimental design that explore the level of pain in preterm infants and effectiveness of the nursing intervention facilitated tucking. Collectively 110 studies were searched out of which 76 relevant and updated studies within the duration of the year 2010-2015 were utilised to support the current research topic. Among the selected 76 supportive studies, 64 were International and 12 were Indian literatures.

The aim of this extensive search of literature review was to identify the intensity and perception level of pain among preterm infants and to determine the effectiveness of facilitated tucking in reduction of level of pain during routine painful procedures. The intention of this review of literature is to gather the best evidences and to derive better understanding of various aspects of the intervention to improve the quality of simple and safe pain relief measure in preterm infants.

For the purpose of logical and systematic sequence the chapter is divided into the following sections.

2.1.1 Scientific reviews related to level of pain in preterm infants.

2.1.2 Scientific reviews related facilitated tucking.

2.1.1 SCIENTIFIC REVIEWS RELATED TO LEVEL OF PAIN IN PRETERM INFANTS

- **Pain in preterm infants**

Researchers Jane Cooper Evans (2010) studied that peripheral and ascending pain pathway are mature by 20 weeks of gestation placing preterm infants capable of experiencing pain and expressions of pain are well documented. Preterm neonates possess immature descending pain pathway and lack serotonin until 6-8 weeks of life making them experience more pain than that of adults. The duration of pain is longer and the consequence of repeated painful stimuli creates permanent structural changes in the vulnerable nervous system of the preterm infant. Multiple researchers (Melanie 2010; Serge Marchand et al. 2010 ; Louis Couturier 2010; Sophie Nadeau 2011) found that preterm birth is associated with stay at NICU that are scheduled with frequent painful procedures such as intubations , blood samplings that occur at a developmental period during which pain transmission mechanisms are well developed.

Series of studies (Smith GC, et al. 2010; Synnes A, et al. 2010; Ruth EG, et al. 2013) on preterm infants during their life in NICU from weeks to months revealed that they are exposed to a high number of life-saving skin-breaking procedures and interventions, as well as routine handling that elicit behavioural, physiological, and hormonal responses that are associated with changes in brain structure and function which contributes to the etiology of neurodevelopmental and behavioural problems in children at later life. A number of unique studies Kenneth D. Craig (2010); Linda A. Hatfield (2012) showed that the common painful diagnostic, medical, and minor therapeutic procedures performed in the NICU were venipunctures, heel lances, immunizations, and central venous catheter insertion are a significant portion of painful events experienced by infants that are often underestimated and under treated showing long-term changes in terms of pain perception and related behaviours.

Carbajal R, Rousset A, Danan C, (2010) in a multicentre study, at tertiary NICU found that preterm infants experienced 60,969 first-attempt procedures over a four month period; 42,413 procedures (69.6%) were identified as painful, 18,556 (30.4%) were considered stressful, each preterm infant was exposed to a median of 75 painful procedures during the study period and had at least 10 painful procedures per day of hospitalization. Sharyn Gibbins, (2010); Timothy G Vedder (2015) in their cross sectional study reported that common painful procedures performed in preterm neonates includes heel pricks or needles sticks, intravenous insertions, suctioning of mouth and nose, lumbar punctures, and intramuscular injections among which heel stick is a minimally invasive and easily accessible way of obtaining capillary blood samples for various laboratory tests and preterm infants are exposed to multiple or frequent blood sampling as a part of clinical care hence the development of pain relief measures and less painful lancing devices may decrease the level of pain in preterm.

Lagercrantz H, et al. (2010) explored the fact that repeated exposure to pain in preterm infants causes rapid changes in the brain development and programming of the hypothalamic-pituitary-adrenal axis that leads to the formation of new synaptic connections extending permanent changes in the neurophysiology during later part of childhood.

Indian researcher Krishnan L, (2013) in his study observed pain in preterm neonates as an ubiquitous phenomenon experienced in the initial days of life, are constantly exposed to pain or noxious stimuli of variable intensity commencing with vitamin K injection and blood collection for sugars, bilirubin or metabolic screening through needle pricks and cannulations till their discharge from the Intensive care units cumulatively resulting in an adverse sequelae in the form of poor neurologic outcomes, abnormal somatization and response to pain later in childhood . Selvam Ramachandran and Sudip Dutta (2013) found that the in-utero early sensory experiences of the fetus are essential for normal brain development during the perinatal period. The premature infant (considered as extra-uterine fetus) is deprived of in-utero sensory experiences, rather exposed to unusual sensory stimuli in the Neonatal Intensive Care Units (NICU) that pose risk to the developing brain in terms of adverse neurodevelopmental outcomes. Murkis S and Subramanian (2011) had

documented that babies born at less than 32 weeks of gestation are exposed to 10–15 painful procedures each day during the first few weeks of life, and in almost 80% no treatment for pain relief is offered; pain in preterm neonates is known to cause adverse short and long-term effects and a host of physiological, biochemical and behavioural responses have been noted during painful episodes.

- **Effects of repeated pain**

Walker SM, et al. (2010) observed that infants born preterm undergo intensive care and experience repeated painful diagnostic and therapeutic procedures in addition with maternal separation**;** They are commonly exposed to lower thresholds of mechanical touch and injured from repeated heel lances for blood sampling during NICU stay that induces long-term neuro-biological and behavioural changes that persist during later part of childhood life. Multiple lines of evidence (Murray RM, and Hack, 2010; M.Synnes AR , et al. 2010) suggested that repeated painful procedures early in life may permanently disrupt the developing central nervous system; cognitive problems remain common and may be increasing, difficulties in attention, executive functions, cognition, language, visual-motor abilities, as well as behaviour problems affect academic performance in children born very preterm, and persist to adulthood. Grunau RE (2010) observed visual-spatial memory problems that are highly prevalent among preterm and appear to be related to altered functional brain activity, characterized by higher ratio of gamma to alpha oscillations.

A prospective study Inder.T et al. (2011) showed that greater exposure to stressful procedures (e.g., heel lance/venipunctures, intubation/ extubation, diaper change) in the NICU was associated with reduced brain size in the frontal and parietal regions in preterm neonates assessed at term-equivalent age. In addition, functional connectivity MRI measures showed that alteration in brain microstructure and functional connectivity within the temporal lobes were related to greater stress exposure in response to repeated painful stimulus among perterm infants. Brummelte S, Grunau, (2012) in a cohort study observed that repeated painful events in the initial pat of neonatal life is independently associated with motor and cognitive development at 8 and 18 months and affects the IQ at age 7 years, and internalizing (depressive, anxiety, somatic symptom) behaviours at school-age. Therefore these evidences support that premature infants

experience grater thresholds of nociceptive pain and has to be managed appropriately with routine nursing care in order to prevent long term consequences of repeated painful stimulus.

- **Assessment of pain in preterm infants**

Reliable pain assessment was one of the first challenges in the pain research of preterm infants, and this challenge still exists today. Multiple Studies (Al Hebabi, J. 2010; Sharyn Gibbins, 2010; American Pain Society, 2012; Krishnan L, 2013.) depicts that pain is a complex sensation and assessment of pain in preterm infants is crucial, that based on bio-behavioural indicators such as increased temperature, blood pressure, heart rate, oxygen consumption, and facial expressions as like grimace, eyes squeeze, nasolabial furrow, mouth stretched open with a tensed and curled tongue, limb movements and varying degree of crying duration. In addition to these responses, a couple of researchers (Al Hebabi, J. 2010; Scopel E, Alencar M, Cruz RM, 2010; Sharyn Gibbins, 2010) found that infant's sleep, waking states, blood pressure, breathing rate, skin colour, widened pupils, sweating also indicators pain in preterm infants.

Several tools are implemented to assess the pain of preterm infants (Pereira Da Silva, 2010; Liaw JJ, et al. 2012 Jan) enforced on Pain Assessment Scale for Preterm Infants (PASPI) scale which uses the transition between the sleep-wake states, facial expressions, changes in heart rate and oxygen saturation, body and limb movements. Pereira Da Silva T, (2010) found that Pain Assessment Tool (PAT) evaluates facial expressions, crying, posture, sleep, perception of the nurse, skin colour, heart rate, breathing pattern, blood pressure and oxygen saturation. (Pereira Da Silva T, 2010; Manworren RC, Hynan LS (2011) reported that the NFCS (Neonatal Facial Coding System) and the Face, Legs, Activity, Cry, Consolability (FLACC) scales evaluated acute and prolonged pain, while NFCS uses only aspects of facial expression such as forehead and squinted eyes, deepening of the nasolabial furrow and horizontal mouth stretch and FLACC measures pain using all types of behavioural indicators: facial expression, lower limb movements, bodily activity, crying and difficulty in consoling the infant. The NIPS (Neonatal Infant Pain Scale) determines the facial expression, crying, breathing patterns, upper limb movements, lower limb movements and state of alertness. (Pereira Da Silva T, 2010; Stevens B, Johnston C, et al. 2010; Gleicia Martins de Melo

2014) demonstrated that Premature Infant Pain Profile (PIPP) scale assesses gestational age, state of alertness, heart rate, oxygen saturation and facial expression (frowning, closed eyes, deepening of the nasolabial furrow). Among all the dimensional scales to assess the intensity of pain PIPP scale is the only multidimensional scale that, among its indicators, includes gestational age specially designed to evaluate pain preterm newborn.

2.1.2 SCIENTIFIC REVIEWS RELATED FACILITATED TUCKING:

- **Facilitated tucking**

A growing volume of evidence (Lim Chin Theam, 2010; Norsiah Rahma, 2010; Jen-Jiuan Liaw,2011; Campbell-Yeo M, et al. 2011 Olive Lopez, 2012; Tayebe Reyhani, et al. 2015) shows that preterm neonates are exposed to a myriad of invasive, often painful, procedures throughout their stay in the neonatal intensive care unit and facilitated tucking (technique of positioning the preterm infants laterally, arms and legs flexed to the midline of the trunk) was able to reduce pain scores significantly and enhance bio-behavioural stability therefore these studies suggest that nurses must be able to carry out facilitated tucking during painful procedures to prevent negative consequences of repeated painful stimuli. Karen E. Corf, et al. (2010) extended his findings that premature neonates will have less variation in heart rate and haemoglobin oxygen saturation, shorter crying and less fluctuation in sleep states in response to the painful stimulus of a heel stick with facilitated tucking than without. Hence these studies serve as ample evidences that facilitated tucking is a simple and effective non-pharmacological pain relief measures that can be routinely practiced during painful procedures with minimal nursing efforts.

S Kucukoglu, (2015) added that facilitated tucking prompt infants own regulatory systems, prevent painful stimulants, reduces the pain felt by the infant by enabling heat and touching stimuli, stabilizes infants physiological parameters and helps them gain a feeling of safety based on the position, supports their motor development, and preserves their energy during the painful procedures.

Mona Alinejad-Naeini, et al. (2014) demonstrated that premature infants between gestational ages of 26-36 weeks are exposed to multiple frequency of endotracheal suctioning and it is impossible to use pharmacological methods of pain

relief; frequent use of facilitated tucking position is a safe and confined technique for procedural pain management which has no adverse effects. (Anna Axelin, et al. 2010; Keira P. Mason,2014) trailed on Facilitated Tucking by Parents (FTP) where a parent holds the infant by her or his hands in a side-lying, flexed foetal-type position, offering support and skin contact firmly before, during and after the painful procedure; it takes from one to two minutes for the infant to adapt and relax under the new sensorial stimulation; therefore, it is recommended that tucking is applied at least two minutes before the painful stimulus. FTP was perceived positively and was used by all participating mothers; however, the type of involvement in pain management is dependent on the mother and her experiences before and during NICU admission. The study recommended nurses to consider maternal factors when involving mothers in the pain care of preterm infants.

Indian researchers (Joseph.JA, 2012; Varghese.B, 2010, Karuthan Chinna, 2014) has experimented the pain relief nursing measure facilitated tucking on preterm newborns born before 37 weeks of gestation and found that facilitate tucking significantly reduced the heart rate, pain scores, behavioural responses and increased oxygen saturation levels comforting the preterm newborn to have self-regulated response over repeated painful stimulus during heel lancing hence enforced to promote facilitated tucking as a routine part of painful procedures

- **Other non-pharmacological pain relief measures on preterm infants**

Researchers have explored various non-pharmacological interventions to manage procedural pain in preterm infants.(Liaw JJ, Yang L, Ti Y, Blackburn ST, Chang YC, Sun LW, 2010; Sharyn Gibbins, 2010) Non-nutritive sucking with appropriate-sized sterile pacifier for comfort sterile during invasive procedures effectively reduced pain, particularly mild to moderate pain and behavioural responses to pain in infants receiving heel stick procedures, suggesting that nurses can offer this intervention to relieve pain in preterm infants undergoing invasive procedures. A group of researchers (Yamada J, Ohlsson, 2010; Denise Harrison, Simon Beggs, 2010; Stevens Bonnie 2012) evaluated the use of oral sucrose in dosages of 0.5–2 ml of 12%–50% solution among 26-36 weeks of gestation approximately one to two minutes prior to single heel lance is effective in providing pain relief in both term and preterm infants however these studies added that

usage of sucrose over longer periods for infants born very preterm needs to be evaluated in further studies.

A set of investigators (Jens Schollin 2011; Kelly Bonyata, 2011; Mei-Chen Ou-Yang,et.al, 2012; F Sabety,et al. 2013) in their trails among preterm of 24- 36 weeks of gestation evaluated the effects of administering 2-5ml of expressed breast milk to the preterm neonates 2 minutes before and after heel lancing and found significant reduction in the duration of cry after lancing, hence they enforced that expressed breast milk is the safe and natural agents for reducing repeated procedural pain of neonates**.**

Other researchers **(**Badr LK, Abdallah B, et al. 2010; Fernanda de Almeida Maia,et al 2011; Celeste Johnston, 2014; Gao.H,et al. 2015) identified that preterm infants less than 37 weeks of gestation are exposed to repeated painful procedures which may lead to negative consequences; Kangaroo Mother Care before or during and after the painful event offers comfort to such neonates, and statistical reduction in heart rate, the duration of crying and facial grimacing has been established for the treatment of a single painful procedure like heel lancing. Fernanda de Almeida Maia, et al. (2011) had extended that this technique increases the mother-child connection, stimulates breastfeeding, increases parental competence and confidence in handling their baby, providing better thermal control, reducing hospital infection and hospital length of stay in addition to its analgesic effects. (Kassar M, et al. 2010; Fernanda de Almeida Maia, et al. 2011; Celeste Johnston, 2014; Gao .H, et al. 2015) Although Kangaroo Mother Care may be a safe analgesic alternative in preterm infants only in whom it is feasible and assessment of behavioural indicators (facial expressions) remained questionable bias**.**

Various other researchers (Jane Collingwood, 2010; Kumar, M. et al. 2010; Lubetzky, R. et al. 2010; Pillai Riddell RR, 2011; Tarja Polkki and Anne Korhonen, 2011) synthesized the best available evidence related to the effectiveness of music as pain relief measure among infants less than 37 weeks of gestation during painful procedures in the neonatal intensive care unit; regardless of the type of music there was significant improvement in physiological outcomes (e.g. oxygen saturation, heart rate, respiratory rate, and blood pressure), as well as in behavioural state (e.g. crying, facial expression, body movements) and reduction in pain scores. Jane Collingwood, (2010) extended his finding that exposure to music stimulation had many positive effects on

preterm infants, such as it increased daily average weight, formula and caloric intake, and significantly reduced total hospital stays and stress behaviours. However certain researchers (Jane Collingwood, 2010; Kumar, M. et al. 2010) from their trials suggested that music should not be played for more than 15 minutes per session, in order to avoid sensory overload in the preterm infants.

Existing studies of randomized control trials (Hartley, Kelsey, 2014; Miller, Connie S. 2010; Gephart, Sheila M. 2015) supports that pain management are necessary to decrease the potentially unfavourable consequences of early exposure to pain; facilitated tucking is a simple and valuable nursing strategy to manage pain in premature infants as early as 23 weeks of gestation that reduces the expression of pain during painful procedures such as heel stick, venipunctures and endotracheal and it is the power and ethical responsibility of the neonatal nurses to help premature infants to cope with procedural pain.

Very few Indian researchers (Standley J, 2012; A. Allen, 2013) have reported that music therapy is a structured intervention to deliver music with the purpose of achieving pain control in infants born after 20 weeks of gestation (as the structures of the auditory system are formed early in 20 weeks fetal life) which also improves the clinical condition such as improve feeding, decreased length of stay, decreased resting energy expenditure, and increased growth and suggested that nurses and parents could use music therapy to decrease stress in the premature infant. Alpanamayi Bera, Dinesh Munia (2014) explored that Kangaroo mother care (KMC) is a non-conventional low cost method for preterm newborn that provides warmth, touch, and security extensively believed to confer significant reduction in procedural pain preferably during minimal invasive procedures such as heel lancing and venipunctures**.** Riya samuel, (2010) supported that administration of oral sucrose prior to painful procedures is an inexpensive, short acting, non-sedating, easily administered and non-invasive form of pain relief measure that does not require additional training and does not expose the infant to greater risks associated with breast or bottle feeding.

SUMMARY

The above literatures were selected to provide high quality and quantity of evidences that infants born preterm also experience pain since their neurological system is mature enough to sense the noxious stimuli of repeated painful stimulus that causes short term and long term effects during their later part of childhood. Literatures also support that facilitated tucking is the cost effective, simple and practicable non-pharmacological nursing intervention that comforts the preterm infants during painful procedures and reduce the level of pain significantly. During the above review of literature the investigator had felt difficulty in gathering Indian literatures pertaining to topic facilitated tucking. The Indian studies were done in minimal number of samples which did not show effective generalization of the results in preterm population.

CHAPTER 3

RESEARCH METHODOLOGY

RESEARCH METHODOLOGY

This chapter describes the methodology adopted in this study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected hospital, Chennai.

This phase of study deals with research approach, research design, variables, setting of the study, population, sample, criteria for sample selection, sample size, sampling technique, development and description of the tool, content validity, reliability of the tool, pilot study, procedure for data collection, and procedure for data analysis.

3.1. RESEARCH APPROACH

Quantitative Research Approach

3.2. RESEARCH DESIGN

The research design undertaken for this study was a quasi-experimental post-test only research design. According to Polit and Beck (2012) the quasi experimental research design had an element of manipulation but lack at least one of the two properties that characterize true experimental: randomization or control. The quasi experimental designs are generally used to establish the causality (effect of independent variable on dependent variable).

The investigator conducted this study in different settings to prevent contamination and adopted control group in order to show the effectiveness. This made the investigator to undertake quasi experimental design for this study.

- **Manipulation**- the investigator performed facilitated tucking by using sense of touch once on the preterm infant, positioning in lateral side with their arms and legs flexed to the midline of the trunk during the painful procedure as the intervention to the study group.
- **Control**- the investigator introduced control over the experimental situation; the investigator had a control group who followed the hospital routine (verbal pampering) i.e., the neonatal nursing staff pampers verbally using gentle words to those preterm infants who exhibit pain by crying during the painful procedure.

The schematic representation of the quasi experimental study as follows

Group	Intervention (×) (Once during the painful procedure)	Post test (O_1) (After the painful procedure)
Study group	**Intervention: (Facilitated tucking)** The investigator performs warming of hands by rubbing the palm against palm to provide a sense of touch on the preterm infant gently turns the infant to the lateral side and position the arms and legs flexed, to the middle of the trunk. The neonatal nursing staff performs the heel prick procedure on the tucked preterm infant.	Interpretation of level of pain was done using PIPP Scale.
Control group	The preterm infant undergoes heel stick procedure as per the hospital routine (verbal pampering).	

3.3 VARIABLES

3.3.1 Independent Variable

The Independent Variable of this study was facilitated tucking.

3.3.2 Dependent Variable

The dependent variable of the study was the level of pain among preterm infants undergoing painful procedure.

3.3.3 Extraneous Variables

It consisted of gestational age of the preterm infant, gender, weight of the preterm infant, APGAR (Appearance, Pulse, Grimace, Activity, Respiration) score at 5^{th} minute, type of feeds before procedure, mode of feeds, time of last feed, type of drugs prescribed, time of last drug administration, size of the needle, duration of the procedure, length of hospitalization and external stimuli before the painful procedure.

3.4 SETTING OF THE STUDY

The study was conducted in Amma Hospital, Choolaimedu Chennai, 120 bedded multispecialty Hospital with 20 bedded NICU with 2-3 nursing staff per shift and in Sir Ivan Stedeford Hospital, Ambattur, Chennai, which was a 220 bedded Hospital with 6 beds in NICU with 2 nursing staff in each shift. The samples for study and control group was selected from both the settings equally.

3.5 POPULATION

3.5.1 Target population

All preterm infants between 26-36 weeks of gestation undergoing painful procedure, admitted in NICU.

3.5.2 Accessible population

Preterm infants between 26-36 weeks of gestation undergoing painful procedure admitted in NICU at Amma Hospital, Choolaimedu, & Sir Ivan Stedeford Hospital, Ambattur, Chennai.

3.6. SAMPLE

Preterm infants between 26 to 36 weeks of gestation undergoing painful procedure, in NICU at Amma Hospital, Choolaimedu, and Sir Ivan Stedeford Hospital, Ambattur, Chennai was selected (both study and control group) as the samples.

3.7 SAMPLE SIZE

The Sample size consisted of minimum 60 preterm infants (30 samples in study & 30 samples in control group) undergoing painful procedure who fulfilled the inclusive criteria.

3.8 SAMPLING TECHNIQUE

Sampling technique adopted for the study was Non probability purposive sampling technique to assign the samples in study and control group.

3.9 CRITERIA FOR SAMPLE SELECTION

3.9.1 Inclusion criteria

1. Preterm infants between 26-36 weeks of gestation.
2. Preterm infants those who are receiving routine care under open incubator.
3. Preterm infants undergoing only heel prick procedure.

3.9.2 Exclusion criteria

1. Preterm infants those who are critically ill.
2. Preterm infants those who have congenital anomalies.
3. Preterm infants who underwent minor or major surgical procedures.
4. Parents of preterm infants who are not willing to participate in the study.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

After an extensive review of literature, discussion with experts in the field of paediatrics and with the investigator personal experience, PIPP scale was used as a valid tool to collect data for this study.

The tool constructed for the study has two parts:

3.10.1 Data collection tool: This consisted of two sections

Section A: Assessment of demographic Variables.

Section B: Premature Infant Pain Profile (PIPP) Scale.

3.10.2 Intervention tool: Facilitated Tucking.

3.10.1 DATA COLLECTION TOOL

Section A: Assessment of Demographic Variables

A medical record review was done to assess the demographic data**.** It consisted of demographic variables such as gestational age of the preterm infant, weight of the preterm infant, gender, Apgar score at 5^{th} minute, type of feeds, mode of feed, time of last feed, drugs prescribed, time of last drug administration, size of the needle, duration of the procedure, length of hospitalization and external stimuli before the painful procedure.

Section B: Premature Infant Pain Profile (PIPP) Scale

The Premature Infant Pain Profile (PIPP) Scale is a comprehensive assessment tool used for preterm infants. The pain intensity is determined by measuring behavioural indicators such as facial expressions such as brow bulge, eye squeeze and nasolabial furrow, and physiological indicators such as heart rate and oxygen saturation, considering them along with the contextual indicators such as child's gestational age at birth as well as asleep/ wake state. These indicators are scored together to provide an indication of acute pain

Table 3.10.1.1 Premature Infant Pain Profile (PIPP) Scale.

Process	**Indicator**	**0**	**1**	**2**	**3**
	Gestational Age	36 weeks and more	32 – 35 weeks, 6 days	28- 31 weeks, 6 days	27 weeks and less
	Behavioral State	Quite\ Sleep Eyes closed no facial movements	Quiet \Awake Eyes open No Facial Movements	Active\Sleep Eyes Closed Facial Movements	Active\Awake Eyes open Facial Movements
Observe infant for 30 sec	**Heart Rate**	0-4 beats/min Increase	5-14 beats/min Increase	15-24 beats/min Increase	25 beats/min or more Increase
	Oxygen Saturation	92-100 %	89-91%	85-88%	84% or less
	Brow Bulge	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more
	Eye Squeeze	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more
	Nasolabial Furrow	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more
Total score					

Table 3.10.1.2 Pain score interpretation:

Score	Interpretation
0-5	Generally indicates the infant has Minimal or No Pain
6-10	Generally indicates slight to Moderate Pain
>10	May indicate Severe Pain

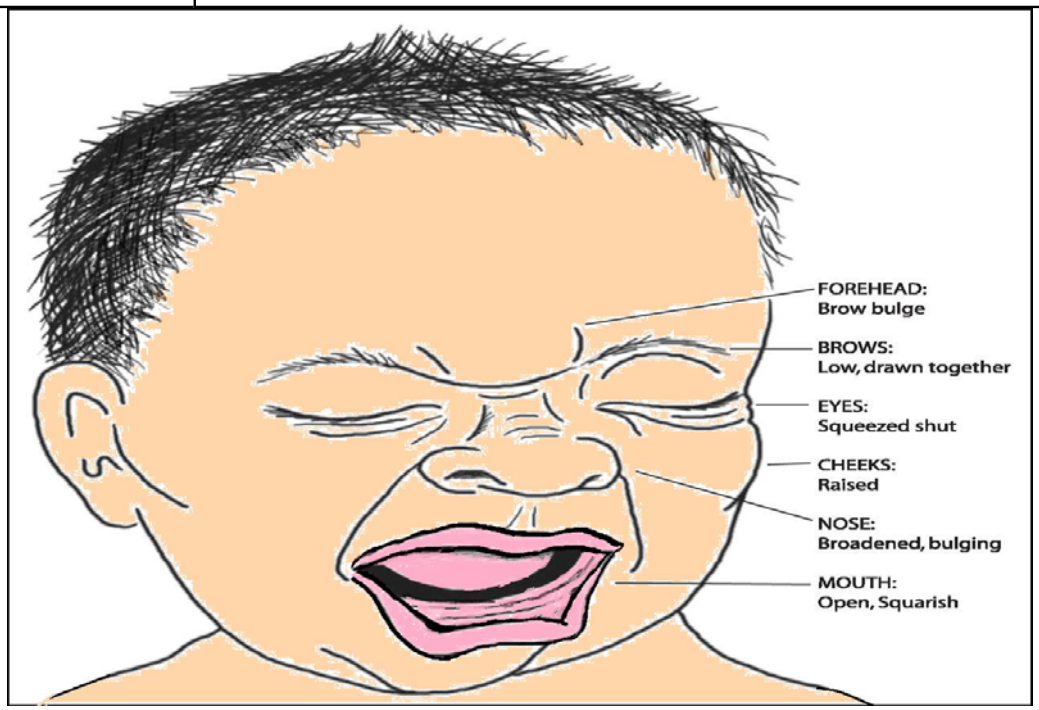


Fig 3.10.1.1 Guide to facial expressions (brow bulge, eye squeeze and nasolabial furrow)

Source: Stevens, B., Johnston, C., Petryshen, P., Taddio, A (2009) Premature Infant Pain Profile (PIPP) Scale.

3.10.2 INTERVENTION TOOL

Name of the intervention	**:**	Facilitated tucking
Time	**:**	30 seconds**.**
Method	**:**	One-to-one.
Indicated client group	**:**	Preterm infants undergoing heel prick procedure.
Venue	**:**	Neonatal Intensive Care Unit (NICU).

Preliminary measures: The investigator established rapport with the parents and explained the procedure as well as the benefits of facilitated tucking on their preterm infants during the painful procedure and obtained informed written consent from the infant's parents. The investigator assessed the demographic variables from the medical records and monitored the hemodynamic status such as heart rate and oxygen saturation level of the preterm infant using calibrated pulseoxymeter as the base line physiological indicator for duration of 15 seconds.

During the procedure: The investigator performed thorough hand hygiene and wore on a sterile apron, cap and face mask as aseptic precautionary measures. The investigator performed warming of hands by rubbing the palm against palm to provide a sense of touch on the preterm infant and gently turned the infant to the lateral side and positioned the arms and legs flexed, to the middle of the trunk. The neonatal nursing staff performed the heel prick procedure on the tucked preterm infant.

After the procedure: The investigator retained the facilitated tucking position and observed the physiological indicator such as maximum heart rate and minimum oxygen saturation level from the calibrated pulse oxymeter for duration of 30 seconds and the behavioural indicators such as asleep/ wake state, brow bulge, nasolabial furrow, eye squeeze were video recorded by the co-staff nurse for the same duration of 30 seconds simultaneously after the painful procedure.

As the preterm infant becomes comfortable (returns back to baseline physiological state and without any behavioral expressions of pain such as eye squeeze, brow bulge and nasolabial furrow) un-tuck the preterm infant and place them in pre-procedural position. The level of pain is interpreted by using PIPP scale.

3.11 CONTENT VALIDITY

The content validity of the scale was ascertained from the following field of expertise

Neonatologist	- 1
Pediatric consultant	- 1
Pediatric Nursing Specialist	- 2

All the experts had given their consensus, the additions and suggestions given by the experts were incorporated in the tool, and the tool was finalized.

3.12 ETHICAL CONSIDERTION

The study was approved by the institutional ethical board of International Centre for Collaborative Research (ICCR), Omayal Achi College of nursing and ethical principles were followed in the study.

(A) BENEFICENCE

- **Freedom from harm and discomfort**

The study participants were prevented from unnecessary risk of harm and discomfort during the study period. The care giver of the preterm infants was given full freedom to disclose their view of discomfort that they feel during the course of the study. No harm certificate was obtained from the neonatologist who ensured that the intervention facilitated tucking is not harmful for the preterm infants.

- **The right to protection from exploitation**

Care givers of the preterm infant were assured that participation of their preterm infant or information provided by them would not be used against them. The investigator completely explained the procedure. The investigator explained the procedure and nature of the study and ensured that the participants in both the study and control group would not be exploited in any cost or denied from fair treatment.

(B) RESPECT FOR HUMAN DIGNITY

The investigator followed the second ethical principle of respect for human dignity. It includes the right to self-determination and right to self-disclosure.

- **The right to self determination**

The investigator has provided full freedom to the care givers of the preterm infants to decide voluntarily about the participation of their preterm infants in the study and the right to ask any question during the course of the study.

- **The right to full disclosure**

The investigator has fully described the nature of the study; the care giver's right to refuse participation and written informed consent was obtained from the parents.

(C) JUSTICE

The investigator adhered to the third ethical principle of justice. It includes participants' right to fair treatment and right to privacy.

- **Right to fair treatment**

The investigator selected the study participants based on the inclusion and exclusion criteria and divided them into study and control group. Both the groups were given equal consideration with regard to safety, privacy, and aseptic technique throughout the study period.

- **Right to privacy**

The investigator maintained the study participant's privacy through confidentiality pledge obtained through written consent from the care givers of the preterm infants and ensured that the video recordings of the facial expressions of each infant are used only to interpret the level of pain and will be discarded immediately after interpretation of the pain score.

(D) CONFIDENTIALITY

The investigator maintained confidentiality of the data provided by the study participants through individual coding for each participant.

3.13 RELIABILITY

The reliability of the tool was done by inter- rater method for level of pain, where 10 preterm infant was selected into study and control group. The tool was assessed by the investigator and equally competent M.Sc. (N) Scholar, at Sir Ivan Stedeford Hospital for all 10 samples. The reliability obtained was 0.8 .The r value indicated positive correlation, which showed that the tool was reliable for the investigator to conduct the main study.

3.14 PILOT STUDY

Pilot study is a trial run for the main study. The refined tool was used for pilot study to test the feasibility and practicability. Data collection procedure was done in Sir Ivan Stedeford hospital, Ambattur, Chennai.

Formal administrative approval was obtained from the International Collaborative Centre for Research (ICCR), principal, Omayal Achi College of Nursing, and from the Medical Directors, Neonatologist, Nursing Supervisor of Sir Ivan Stedeford Hospital, Ambattur, and Chennai. A special permission to record the facial expressions of the preterm infant after the painful procedure and assistance of the staff nurses at the NICU to record the video was also obtained from the medical directors of the institutions. A brief introduction about the self and purpose of the study was explained to care givers and informed consent was obtained ensuring the purpose of video recording of facial expressions of their preterm infants. Confidentiality regarding the data was assured so as to get co-operation throughout the procedure of data collection period.

The data collection was done for a period of one week and the investigator worked from morning 5am to 7am for completion of the scheduled intervention. Based on the inclusion and exclusion criteria 10 samples were selected depending on the number of admissions on daily basis. The samples were assigned 3 in study and 2 in control group on the 1st day, 2 in study and 3 in control group on the 2nd day respectively. The investigator used the PIPP scale to assess the level of pain in preterm infants undergoing painful procedure.

To begin, the investigator assessed the demographic variables from the medical records and the hemodynamic status such as maximum heart rate and minimum oxygen saturation of the preterm infants using calibrated pulse oxymeter as the base line physiological indicator for duration of 15 seconds before the painful procedure. The investigator performed thorough hand hygiene and wore on a sterile apron, cap and face mask as an aseptic precautionary measure. The investigator performed warming of hands by rubbing the palm against palm to provide a sense of touch on the preterm infant, gently turned the infant to the lateral side and positioned their arms and legs flexed, to the middle of the trunk .The neonatal nursing staff performed the heel-prick procedure

on the tucked preterm infant. The facilitated tucking position is retained after the painful procedure and the physiological indicators such as maximum heart rate and minimum oxygen saturation levels were observed by the investigator from the calibrated pulse oxymeter for duration of 30 seconds after the procedure whereas the behavioural indicators such as asleep/ wake state, brow bulge, nasolabial furrow, eye squeeze were video recorded by the co-staff nurse for the same duration of 30 seconds simultaneously after the painful procedure.

As the preterm infant becomes comfortable (returns back to baseline physiological state and without any behavioral expressions of pain such as eye squeeze, brow bulge and nasolabial furrow) un-tuck the preterm infant and place them in pre-procedural position. The level of pain was interpreted by PIPP scale.

3.15 PROCEDURE FOR DATA COLLECTION

Data collection was done at in Neonatal Intensive Care Units of Amma Hospitals Choolaimedu Chennai, and in Sir Ivan Stedeford Hospital, Ambattur Chennai. Formal administrative approval was obtained from the International Collaborative Centre for Research (ICCR), principal, Omayal Achi College of Nursing. Approval from the administrators, Medical Directors, Neonatologist, Nursing Supervisor of Amma hospital, Choolaimedu, Chennai, and Sir Ivan Stedeford Hospital, Ambattur, Chennai was obtained by the investigator prior to the study. A special permission to record the facial expressions of the preterm infant after the painful procedure and assistance of the staff nurses at the NICU to record the video was also obtained from the medical directors of the institutions. The investigator self-introduced and briefed the parents of preterm infants about the benefit of the selected cost-effective nursing measure. The parents were also ensured on the video recording of facial expressions of their preterm infants followed by which the informed consent was obtained.

The data collection was done for a period of six weeks and the investigator worked from morning 5am to 7am in the morning at Amma Hospital, Choolaimedu, Chennai, and 5pm to 7pm in the evening at Sir Ivan Stedeford Hospital, Ambattur, Chennai, for completion of the scheduled intervention. Based on the inclusion and

exclusion criteria samples for the study were selected depending on the number of admissions on daily basis. The investigator assigned the samples into study and control group based on the availability of clinically stable preterm infants each day. Pair matching was done for the gestational age of the preterm infant. The samples in study group were given the intervention of facilitated tucking as the simple pain relief nursing measure during the painful procedure under strict aseptic technique and the control group were allowed to undergo the usual verbal pampering which was the hospital routine. The investigator used the PIPP scale to assess the level of pain in preterm infants undergoing painful procedure.

Preliminary measures:

The investigator performed the intervention for those selected infants undergoing painful procedure. The demographic variables were assessed from the medical records and the hemodynamic status such as maximum heart rate and minimum oxygen saturation level of the preterm infants using calibrated pulse oxymeter as the base line physiological indicator for duration of 15 seconds.

During the procedure:

The investigator performed thorough hand hygiene and wore on a sterile apron, cap and face mask as aseptic precautionary measures. The investigator performed warming of hands by rubbing the palm against palm to provide a sense of touch on the preterm infant, gently turned the infant to the lateral side and positioned the arms and legs flexed, to the middle of the trunk. The neonatal nursing staff performed the heel-prick procedure on the positioned preterm infant.

After the procedure:

The investigator retained the facilitated tucking position of the preterm infant after the painful procedure and assessed the physiological indicators such as maximum heart rate and minimum oxygen saturation levels by the calibrated pulse oxymeter for duration of 30 seconds whereas the behavioural indicators such as asleep/ wake state, brow bulge, nasolabial furrow, eye squeeze were video recorded by the co-staff nurse for the same duration of 30 seconds simultaneously after the painful procedure. As the preterm infant becomes comfortable (returns back to baseline physiological state and

without any behavioral expressions of pain such as eye squeeze, brow bulge and nasolabial furrow) un-tuck the preterm infant and place them in pre-procedural position. The level of pain is interpreted by using PIPP scale.

For the preterm infants in control group who underwent painful procedure by verbal pampering as the hospital routine, the investigator assessed the physiological indicators such as maximum heart rate and minimum oxygen saturation levels using the same calibrated pulse oxymeter and the behavioural indicators such as asleep/ wake state, brow bulge, and nasolabial furrow, eye squeeze were video recorded simultaneously for duration of 30 seconds after the painful procedure.

Interpretation:

The level of pain was assessed by PIPP Scale for both the groups. Preliminary observation was made and gestational age of the preterm infant was identified from the medical record. Preterm infants with the gestational age of 36 were scored with the pain score of 0, whose gestational age was between 32-35 were scored with pain score of 1, preterm infants with the gestational age of 28-3 were scored with the pain score of 2 and those who were below 27 weeks of gestation were scored with the pain score of 3. Physiological indicator of the preterm infant such as maximum heart rate and the minimum oxygen saturation level assessed after the painful procedure for duration of 30 seconds was compared with the maximum heart rate and the minimum oxygen saturation level which was recorded for duration of 15 seconds before the painful procedure to determine the number of increased beats in heart rate and decrease in level of oxygen saturation.

Preterm infants who had 0-4 beats increase in 30 seconds was scored as 0; who had 5-14 beats increase in 30 seconds was scored as 1; who had 15-24 beats increase in 30 seconds were scored as 2 and who had 25 beats increase and more were scored with the pain score of 3. In the same way preterm infants whose oxygen saturation level were in the range of 92-100% was given the score of 0, who were in the range of 89-91% was scored as 1, who were in the range of 85-88% was scored as 2 and who were with decreased saturation level of 84% and less was scored with the pain score of 3.

The behavioural indicators was interpreted by the facial expressions of the preterm infants which was video recorded for 30 seconds after the painful procedure. The 30 second video of each sample was played for three consecutive times to determine the duration of each facial expression such as brow bulge, eye squeeze and nasolabial furrow. The percentage of the facial expression was calculated by the following formula

$$\text{Time of facial expression in percentage} = \frac{\text{Duration of the single expression}}{\text{(Standard duration of observation as per PIPP scale)}} \times 100$$

The preterm infants who exhibited expressions for 0-9% were scored as 0, who exhibited expression for 10-39% were scored as 1, who exhibited 40-69% of expressions were scored as 2 and who expressed for 70% and more were scored with the pain score of 3. Cumulative scores of both physical and behavioural indicators were summed up and total pain score was derived.

The total pain score of preterm infants was interpreted as below:

0-5 - No pain or Mild pain

6-10 - Moderate pain

> 10 - Severe pain

3.16 PLAN FOR DATA ANALYSIS

The data collected was analysed using both descriptive and inferential statistics

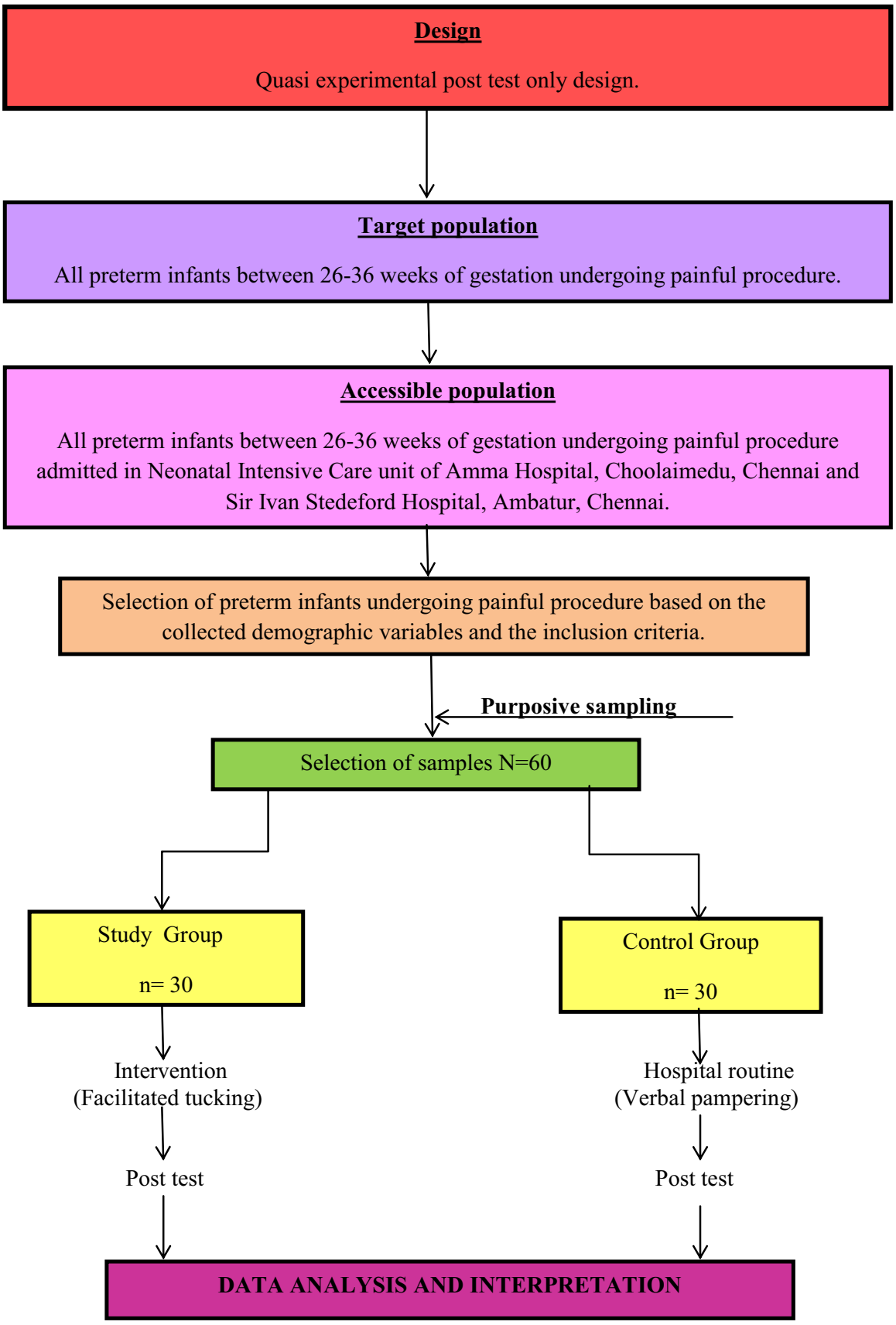
3.16.1 Descriptive Statistics

1. Frequency and percentage distribution was used to analyse the demographic variables
2. Mean and standard deviation was used to analyse the post test level of pain among preterm infants undergoing painful procedure.

3.16.2. Inferential Statistics

1. Unpaired ‘t’ test was used to compare the post-test level of pain among preterm infants undergoing painful procedure in the study and control group.
2. One way ANOVA was used to associate the selected demographic variables with the post test mean pain score among the study and control group.

SCHEMATIC REPRESENTATION OF RESEARCH METHODOLOGY



CHAPTER 4

DATA ANALYSIS AND INTERPRETATION

DATA ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of the data collected from 60 preterm infants (30 in study and 30 in control group) undergoing painful procedure at selected settings, Chennai. The data was collected, organized, tabulated and analysed according to the objectives. The findings based on the descriptive and inferential statistical analysis are presented under the following sections.

ORGANIZATION OF THE DATA

Section 4.1: Description of the demographic variables of the preterm infants in the study and the control group.

Section 4.2: Assessment and comparison of post test level of pain among preterm infants undergoing painful procedure between the study and control group.

Section 4.3: Association of the selected demographic variables with the post test mean pain score among preterm infants undergoing painful procedure in the study and control group.

SECTION 4.1: DESCRIPTION OF THE DEMOGRAPHIC VARIABLES OF THE PRETERM INFANTS IN THE STUDY AND THE CONTROL GROUP.

Table 4.1.1: Frequency and percentage distribution of demographic variables of preterm infants undergoing painful procedure in study and control group with respect to gestation age in weeks, gender, weight in grams, APGAR score at 5th minute and type of feed before the painful procedure.

N=60

S.No.	Demographic variables	Study Group (Facilitated tucking) n= 30		Control Group (Hospital routine) n= 30	
		No.	%	No.	%
1.	**Gestational Age in weeks**				
	26 – 28	-	-	-	-
	29 – 31	02	06.7	02	06.7
	32 – 34	09	30.0	09	30.0
	35 – 36	**19**	**63.3**	**19**	**63.3**
2.	**Gender**				
	Male	**17**	**56.7**	**15**	**50.0**
	Female	13	43.3	15	50.0
3.	**Weight in grams**				
	< 1500	03	10.0	06	20.0
	1500-2000	**14**	**46.7**	**13**	**43.3**
	2000-2500	13	43.3	11	36.7
4.	**APGAR score at 5th minute**				
	5-7	09	30.0	09	30.0
	>7	**21**	**70.0**	**21**	**70.0**
5.	**Type of feed before painful procedure**				
	Breastfeed	**16**	**53.3**	**15**	**50.0**
	Formula feed	06	20.0	02	06.7
	Breastfeed and formula feed	03	10.0	13	43.3
	Others (on Nil Per Oral)	05	16.7	-	-

The above table 4.1.1 shows that majority of the preterm infants were in the gestational age of 35-36 weeks, male, weighing between 1500-2000 grams with APGAR score of >7 at the 5th minute and was breast fed before the painful procedure in both study and control group.

Table 4.1.2: Frequency and percentage distribution of demographic variables of preterm infants undergoing painful procedure in study and control group with respect to mode of feed, time of last feed, drugs prescribed, time of last drug administration and size of the needle.

N=60

S.No.	Demographic variables	Study Group (Facilitated tucking) n= 30		Control Group (Hospital routine) n= 30	
		No.	%	No.	%
1.	**Mode of feed**				
	Oral feed	**19**	**63.3**	**15**	**50.0**
	Nasogastric tube feed	06	20.0	14	46.7
	Parenteral feed	05	16.7	01	03.3
2.	**Time of last feed**				
	< 15 minutes	02	06.7	03	10.0
	15-30 minutes	02	06.7	04	13.3
	30 min- 1 hr.	09	30.0	07	23.3
	> 1 hr.	**17**	**56.7**	**16**	**53.3**
3.	**Drugs prescribed**				
	Analgesics	-	-	-	-
	Antibiotics	**30**	**100.0**	**29**	**96.7**
	Sedative	-	-	-	-
	Others	-	-	01	03.3
	Combination of drugs	-	-	-	-
4.	**Time of last drug administration**				
	< 15 minutes	05	16.7	02	06.7
	15-30 minutes	01	03.3	02	06.7
	30 min- 1 hour	01	03.3	-	-
	> 1 hour	**23**	**76.7**	**26**	**86.7**
5.	**Size of the needle**				
	28 gauge	**17**	**56.7**	13	43.3
	26 gauge	13	43.3	**17**	**56.7**
	24 gauge	-	-	-	-

The above table 4.1.2 shows that most of the preterm infants had been fed orally; the time of last feed was more than 1 hour, received antibiotics before 1 hour and was pricked with 28 gauge size needle in the study group. In context to control group the preterm infants had been fed orally, before 1 hour, most of them received antibiotics before 1 hour and were pricked with 26 gauge size needle in the control group.

Table 4.1.3: Frequency and percentage distribution of demographic variables of preterm infants undergoing painful procedure in study and control group with respect to, duration of the procedure, length of hospitalization and external stimuli before the painful procedure.

N=60

S.No.	Demographic variables	Study Group (Facilitated tucking) n= 30		Control Group (Hospital routine) n= 30	
		No.	**%**	**No.**	**%**
1.	**Duration of the procedure**				
	< 1 minute	**27**	**90.0**	**30**	**100.0**
	1-2 minute	03	10.0	-	-
	>2 minute	-	-	-	-
2.	**Length of hospitalization**				
	Newly admitted.	**13**	**43.3**	**12**	**40.0**
	1-2 days	12	40.0	11	36.7
	3-4 days	04	13.3	05	16.7
	> 4days.	01	3.3	02	06.7
3	**External stimuli before the painful procedure**				
	Absent	**29**	**96.7**	**27**	**90.0**
	Present	01	03.3	03	10.0

The above table 4.1.3 shows that the duration of the painful procedure was <1 minute, most of them were newly admitted and were not exposed to any external stimuli before the painful procedure in the study group. However the duration of the procedure and length of hospitalization was similar to study group while few preterm infants were exposed to some external stimuli before the painful procedure in the control group.

SECTION 4.2: ASSESSMENT AND COMPARISION OF POST TEST LEVEL OF PAIN AMONG PRETERM INFANTS UNDERGOING PAINFUL PROCEDURE BETWEEN THE STUDY AND CONTROL GROUP.

N=60

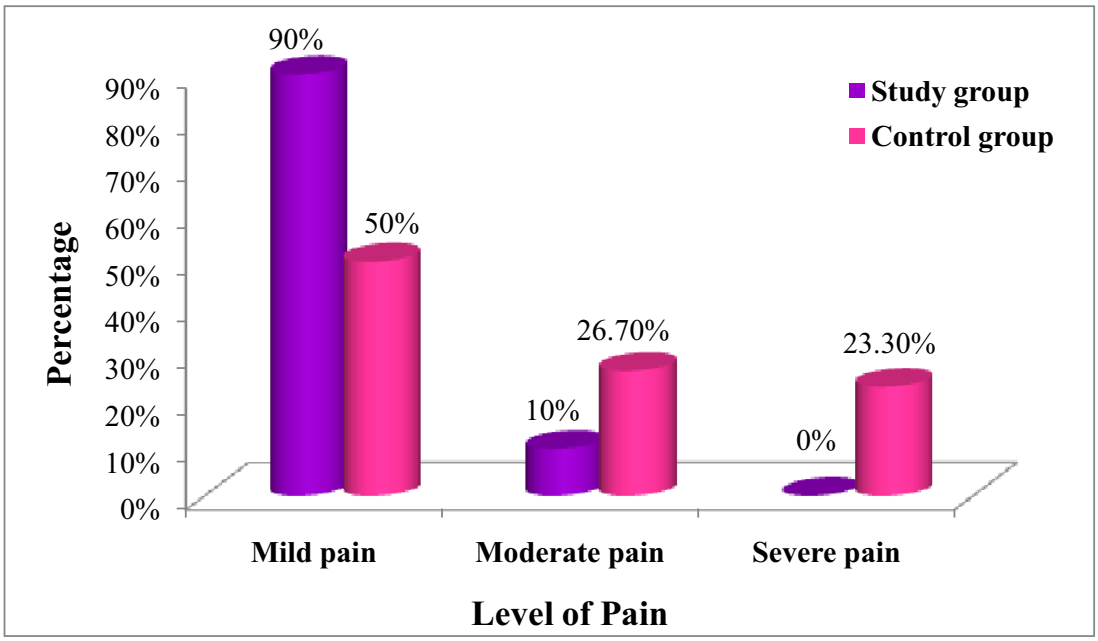


Fig.4.2.1: Frequency and percentage distribution of level of pain between study and control group.

The above figure shows that the preterm infants those who were given the nursing intervention of facilitated tucking during the painful procedure experienced mild to moderate pain while none of them experienced severe pain; however the preterm infants those who underwent the hospital routine (verbal pampering) experienced mild to severe pain which depicts that facilitated tucking during painful procedures will reduce the level of pain experienced by the preterm infants.

Table 4.2.2: Comparison of post test level of pain between study and control group.

N=60

Group	Mean	Standard Deviation	Unpaired "t" test Score
Study	3.267	2.7409	**"t" = -5.051 at p<0.000*** **
Control	8.367	4.8029	

*** - High Statistical Significance at p<0.001 level.

The above table 4.2.2 shows that mean pain score of post-test level of pain in the preterm infants who underwent painful procedure with facilitated tucking was significantly less than mean pain score of post-test level of pain in the preterm infants who underwent painful procedure in the hospital routine (verbal pampering). The calculated unpaired "t" test value was -5.051 which was found to be highly statistically significant at p<0.001 level which indicates that the preterm infants who were given the nursing intervention facilitated tucking was comfortable, more secure with controlled response and also had reduced pain during painful procedures.

SECTION 4.3: ASSOCIATION OF THE SELECTED DEMOGRAPHIC VARIABLES WITH THEIR MEAN SCORE LEVEL OF PAIN AMONG PRETERM INFANTS UNDERGOING PAINFUL PROCEDURE IN THE STUDY AND CONTROL GROUP.

N=60

S.No.	Demographic variables	ANOVA Score			
		Study group (Facilitated tucking) n=30		Control group (Hospital routine) n=30	
		F	Sig	F	Sig
1.	Gestational age	.011	.987	.321	.728
2.	Gender	.211	.649	2.29	.141
3.	Weight in grams	2.26	.124	.530	.594
4.	APGAR score at 5th minute	.267	.609	.512	.480
5.	Type of feed before painful procedure	.741	.537	**2.84**	**.076**
6.	Mode of feed	.569	.573	2.36	.113
7.	Time of last feed	.315	.814	.731	.543
8.	Drugs prescribed	.009	.923	.514	.604
9.	Time of last drug administration	1.89	.155	1.73	.195
10.	Size of the needle	1.00	.324	1.91	.177
11.	Duration of the procedure	.030	.863	-	-
12.	Length of hospitalization	.787	.512	**6.79**	**.002****
13.	External stimuli before the painful procedure	1.98	.170	**10.1**	**.004****

**-High Statistical significance at p<0.001 level.

The table 4.3.1 shows that there was no association of the selected demographic variables with their mean score level of pain among preterm infants undergoing painful procedure in the study group whereas the demographic variables such as type of feed before the painful procedure shows near significance, length of hospitalization and external stimuli before the painful procedure showed statistical significance in control group.

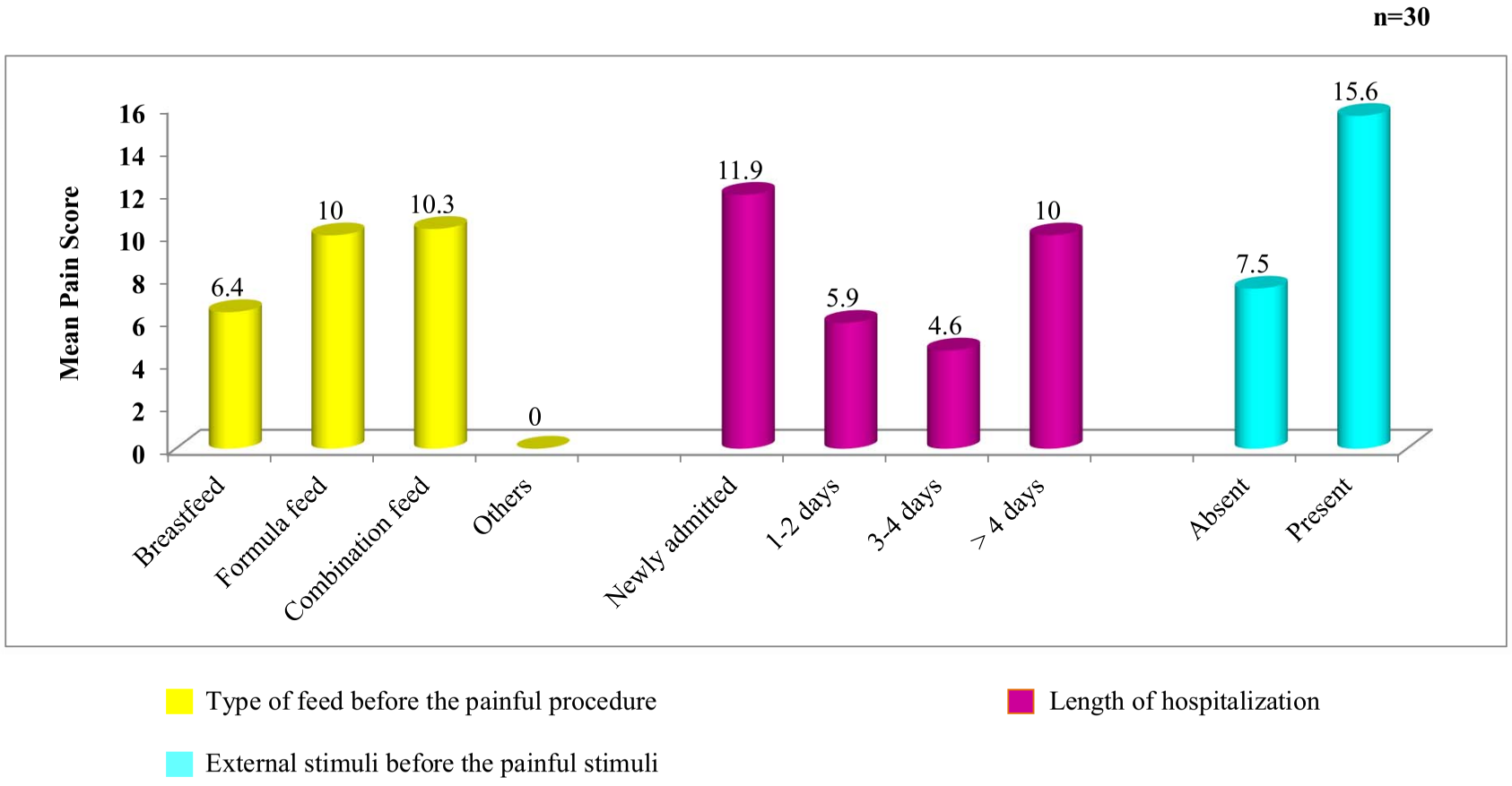


Figure 4.3.1: Association of mean differed pain score with selected demographic variables of control group (One way ANOVA)

The figure 4.3.1 shows that preterm infants experience less pain when breastfed than formula feed or combination of both feeds. Newly admitted preterm infants are highly sensitive to painful procedures and experience more pain. Preterm infants who were stimulated externally before the painful procedure showed increased level of pain.

CHAPTER 5

DISCUSSION

DISCUSSION

This chapter discusses in detail the findings of the study as interpreted from the statistical analysis, in accordance with the objectives of the study and further discussion will illustrate the fulfilment of the objectives by the study findings. The purpose of the study was to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure.

As per the stated objectives the findings of the study were discussed.

5.1 Description of the demographic variables among the preterm infants undergoing painful procedure in study and control group.

The demographic variables of both the study and control group as shown in the table 4.1.1 to 4.1.3 depicts that majority of the preterm infants were with the gestational age of 35-36 weeks, male, weighing between 1500-2000grams with APGAR score was >7 at the 5^{th} minute and was breast fed orally before an hour of painful procedure, received antibiotics before 1 hour, was pricked with 28 gauge size needle; the duration of the painful procedure was <1 minute, most of them were newly admitted and were not exposed to any external stimuli before the painful procedure in the study group

In context to control group the preterm infants had similar categorization of demographic variables as like the study group with regards to gestational age, gender, weight, APGAR score at 5^{th} minute, type of feed, mode of feeds, time of last feed, type and last time of drug administration, duration of the painful procedure and length of hospital stay which showed homogenesity between the groups among these. However few preterm infants were pricked with 26 gauze size needle and exposed to some external stimuli before the painful procedure in the control group which makes them differed from the study group.

5.2 The first objective of the study was to assess and compare the post- test level of pain among the preterm infants undergoing painful procedure in study and control group.

The figure 4.2.1 showed that the preterm infants those who were given the nursing intervention facilitated tucking during the painful procedure experienced mild to moderate pain while none of them experienced severe pain; however the preterm infants those who underwent the hospital routine (verbal pampering) experienced mild to severe pain which depicts that facilitated tucking during painful procedures was reduce the level of pain experienced by the preterm infants.

The preterm infants who were in the range of 0-5 pain score in the PIPP scale where interpreted to have mild pain. The preterm infants who underwent painful procedure with facilitated tucking experienced the pain score in the range of (0-3); these preterm infants neither had elevation of heart rate, decrease in oxygen saturation level nor showed any facial expressions of pain however they was scored with pain score of 1 and 2 with regards to their decrease in gestational age as per PIPP scale. Whereas half of the samples (15 samples) in control group who underwent painful procedure in the hospital routine (verbal pampering) had experienced mild pain in the range of (4 and 5) pain score; these preterm infants with their decrease in gestational age also had elevation of heart rate, decrease in oxygen saturation level with minimal duration of facial expressions of pain.

The results of the study are supported by (Mona Alinejad-Naeini, et al. 2012; Balasubramanian Sundaram and Vijay Pratap Singh., 2013) in their Randomized Controlled crossover study to assess the effects of facilitated tucking on procedural pain in preterm neonates using PIPP scores. The results showed that most of the infants experienced severe pain during procedures without intervention but very few of them experienced severe procedural pain with intervention and concluded that the facilitated tucking position can be used as a safe non-pharmacological method of pain relief in preterm neonates.

The table 4.2.2 showed the comparison of post test level of pain between study and control group. As depicted in the table the post test mean pain score in the preterm infants who underwent painful procedure with facilitated tucking was significantly less than mean pain score of post test level of pain in the preterm infants who underwent painful procedure in the hospital routine. The nursing intervention facilitated tucking which was performed by positioning the preterm infants laterally with their arms and legs flexed to the midline of the trunk during painful procedure simulated a comfortable condition of being in uterus and secured them with controlled response to painful stimulus. The calculated unpaired "t" test value was -5.051 which was found to be highly statistically significant at $p<0.001$ level which indicates that facilitated tucking has effectiveness in reducing pain during procedures.

Thus the null hypothesis NH_1 stated earlier that **"There is no significant difference between the level of pain among preterm infant in study and control group at p <0.05 level"** was rejected.

Researchers (Tayebe Reyhani, Seyedeh Zahra Aemmi, Tahere Mohebbi, Hasan Boskabadi, 2014; Sibel Kucukoglu ,2015) in their semi-experimental study assessed the effectiveness of facilitated tucking on crying duration of preterm infants born at average 32 to 36 weeks of Gestation during blood collection and Hepatitis immunization procedure and the suggested that facilitated tucking is a simple non-pharmacological nursing measure that alleviates pain and duration of crying which the nurses must carry out during blood sampling.

The conceptual framework adopted for this study was Kolcaba's theory of comfort, which supported the study and was helpful for the investigator to accomplish the study through an organized process. At the beginning, the investigator identified pain during the procedures as the health care needs of the preterm infants. Based on the identified need the investigator planned facilitated tucking as the comforting measure. The investigator combined the health care need and the comforting measure which led to the attainment of enhanced comfort through relief (level of pain), ease (facilitated tucking) and transcendence (reduction in the level of pain) which was assessed by post-

test level of pain. Institutional integrity was formulated for best practices and best policies.

5.3 The second objective was to associate the selected demographic variables with the post test mean pain score among the preterm infants undergoing painful procedure in study and control group.

The findings of the study were analysed using one way analysis of variance for association of demographic variables with the post test mean pain score. As shown in the table 4.3.1 shows that there was no association of the selected demographic variables with their mean pain score among preterm infants undergoing painful procedure in the study group whereas the demographic variables such as type of feed before the painful procedure shows near significance, length of hospitalization and external stimuli before the painful procedure shows statistical significance in control group.

Since breast milk has natural analgesic effect preterm infants who were fed with breast milk before half an hour experienced less pain; preterm infants those who were fed with combination of formula feed and breast milk had insufficiency of meeting the energy needs which subjected them to experience more pain than other infants.

Newly admitted preterm infants were very sensitive to noxious stimuli and experienced more pain than the preterm who stayed in the hospital for more than a day as they had adopted themselves to repeated painful stimulus; preterm infants those who were hospitalized for more than 4 days were subjected to repeated skin breaking and life-saving procedures as part of routine care contributing increased perception of pain than other infants who had minimal hospital stay.

Preterm infants who were manipulated externally (by means of diaper changing, Non Invasive Blood Pressure monitoring, administration of injections, feeding) are awake/ active before the painful procedure and experience more pain than other preterm infants who were in quiet or sleep state.

Hence the null hypothesis NH_2 stated earlier that **"There is no significant association of the selected demographic variables with the mean pain score was accepted in study group and rejected for the selected demographic variables in the control group at p <0.05 level".**

CHAPTER 6

SUMMARY

CONCLUSION

IMPLICATIONS

RECOMMENDATIONS

AND LIMITATIONS

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

This chapter puts forward the summary, conclusion, implications and limitations of the study based on objectives selected.

6.1 SUMMARY

Infants that are born preterm arrive in an untimely manner from the intrauterine environment before their anatomy and physiology are prepared to cope with the extra uterine environment. They are typically hospitalized in a hostile environment of the Neonatal intensive care unit (NICU) where they undergo numerous tissue damaging procedures that are part of clinical care. Pain is an acute stress that can potentially lead to long-term complications. Preterm neonates are more vulnerable to these effects as the painful insult occurs during the brain development, exposing them to possible long-term developmental and psychological problems. Therefore, pain management in preterm neonates is a very important issue in the NICU. There are various clinically proven pain relief measures such as facilitated tucking, swaddling, non-nutritive sucking, oral sucrose solutions, analgesics etc., and the practical approach of managing procedural pain remains a neglected parameter. In order to reduce the long term effect of pain, the researcher conducted this study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedures at selected hospitals, Chennai. The findings of this study proved to be effective in reducing the level of procedural pain among preterm infants.

The objectives of the study were

1. To assess and compare the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure in study and control group
2. To associate the selected demographic variables with the post test mean pain score among preterm infants undergoing painful procedure in study and control group.

The null hypothesis stated were

NH_1- There is no significant difference between the level of pain among preterm infant in study and control group at $p < 0.05$ level.

NH_2- There is no significant association of the selected demographic variables with the post test mean pain score in study and control group at $p < 0.05$ level.

The review of literature was collected from varied primary and secondary sources, along with personal and professional experience and expert's opinion from the field of medical as well as child health nursing that provided an ample framework for the selection of problem and for accomplishing the objectives of the study. It also contributed the ideas for framing the conceptual framework, methodology and for the development of the tool for data collection.

The conceptual framework employed for the study was derived from Kolcoba's theory of comfort.

Quantitative research approach and quasi experimental post-test only research design was adopted by the nurse investigator to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure. The research study was conducted among the preterm infants undergoing painful procedure whoever fulfilled the inclusion criteria at Neonatal Intensive Care Units of Amma Hospital, Choolaimedu, and Sir Ivan Stedeford Hospital, Ambatur, Chennai during the period of data collection. The sample size was 60 who were categorized into 30 in study and 30 in control group by convenient sampling technique.

The tool constructed for the study has two parts:

Section A: Assessment of Demographic Variables

A medical record review was used to assess the demographic data**.** It consisted of demographic variables such as gestational age of the preterm infant, weight of the preterm infant, gender, APGAR score at 5^{th} minute, type of feeds, mode of feed, time of last feed, drugs prescribed, time of last drug administration, type and size of the needle,

number of pricks, length of hospitalization and external stimuli before the painful procedure.

Section B: Premature Infant Pain Profile (PIPP) Scale

The PIPP scale is a comprehensive assessment tool used for preterm infants. The pain intensity is determined by measuring behavioural indicators such as facial expressions such as brow bulge, eye squeeze and nasolabial furrow, and physiological indicators such as maximum heart rate and minimum oxygen saturation, considering them along with the contextual indicators such as child's gestational age at birth as well as asleep/ wake state. These indicators are scored together to provide an indication of acute pain.

The tool was validated by medical and nursing experts. Pilot study was conducted at Sir Ivan Stedeford Hospital, Ambatur, Chennai and the results proved to be practicable and feasible to proceed with the main study. Inter -ratter method was employed to establish the reliability of the tool by using Karl Pearson correlation coefficient method by which the **'r' = 0.8** was obtained and thus the tool was found to be highly reliable to carry on with the main study.

Throughout the research study the ethical aspect was maintained by obtaining the ethical clearance certificate from the International Centre for Collaborative Research (ICCR) and from the Medical Directors, Neonatologist, Nursing Supervisor of Amma Hospital, Choolaimedu and Sir Ivan Stedeford Hospital, Ambattur, Chennai. A special permission to record the facial expressions of the preterm infant after the painful procedure and assistance of the staff nurses at the Neonatal Intensive Care Units to record the video for study group was also obtained from the medical directors of the institutions. A brief introduction about the self and purpose of the study was explained to care givers and informed consent was obtained ensuring the purpose of video recording of facial expressions of their preterm infants. Confidentiality regarding the data was assured so as to get co-operation throughout the procedure of data collection period.

The main study data collection was conducted for a period of 4 weeks. The data collected during the main study was analysed using SPSS version 13.

Main findings of the study revealed that

- Descriptive and inferential statistics were used to analyse the collected data. Interpretation and discussion were based on the objectives, null hypotheses, conceptual framework and from various literature review
- The post test level of pain showed that 27(90.0%) of the preterm infants experienced mild pain, 3(10.0%) experienced moderate pain and none of them experienced severe pain in the study group. Whereas 15(50.0%) of the preterm infants experienced mild pain, 8(26.7%) experienced moderate pain and 7(23.3%) experienced severe pain in the control group.
- The post test mean pain score in study group was 3.267 with the standard deviation 2.7409, whereas the mean pain score in control group was 8.367, with the standard deviation. The calculated unpaired "t" test value t= -5.051 was found to be highly statistically significant at $p<0.001$ level. These values indicate that there was reduction in the post test level of pain among preterm infants who received the intervention facilitated tucking than the post test level of pain among of preterm infants who were allowed to follow the hospital routine on ethical basis.

6.2 CONCLUSION

The present study was aimed to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure. The findings revealed that the mean pain score of post-test level of pain in study group was 3.267 with the standard deviation 2.7409, whereas the mean pain score in control group was 8.367, with the standard deviation. The calculated unpaired "t" test value t= -5.051 was found to be highly statistically significant at $p<0.001$ level. These values indicate that there was reduction in the post test level of pain among preterm infants who received facilitated tucking than the post-test level of pain among of preterm infants who were allowed to follow the hospital routine on ethical basis. Thus the intervention tool can be utilized by the neonatal nursing professionals in their clinical practice to reduce the level of procedural pain in preterm infants at the Neonatal Intensive Care units and Neonatal Wards.

6.3 IMPLICATIONS

The investigator has put forward the following implications from the study which is of crucial concern for nursing practice, nursing education, nursing administration and nursing research.

6.3.1 Nursing practice

1. The pediatric nurses can adopt facilitated tucking as simple, cost-effective, non-pharmacological nursing measure employed in care of preterm infants undergoing painful procedure at their clinical areas of practice.
2. The child health nursing practitioners can formulate a separate protocol for practicing facilitated tucking in their daily routine as procedural pain control measure.
3. Facilitated tucking can be taught and practiced by the primary health care nurses in the primary health care centres as part of their routine procedural pain relief.
4. The pediatric nurse should disseminate the information about facilitated tucking to the caregivers of all preterm infants admitted in the Neonatal Intensive Care Units.

6.3.2 Nursing Education

1. The pediatric nurse being a nurse educator can integrate the major study findings in the nursing curriculum at various levels to build up and train the students to assess the level of pain using the PIPP scale and to prevent the long-term consequences of repeated painful stimuli.
2. The nurse educator must facilitate the student nurses to gain skills required to employ facilitated tucking to procedural pain in preterm infants.
3. The educational institutions must offer opportunities for the nursing students to get exposed to such training programmes.

6.3.3 Nursing Administration

1. This research will be successfully implemented in Amma Hospital, Choolaimedu and Sir Ivan Stedeford Hospital, Ambattur, Chennai.

2. The child health nurse administrator along with the administrative bodies and other health care agencies can devise a program to focus on the measures to control pain during the painful procedures.
3. The nurse administrator within the institution should motivate and train the staff to carry out routine assessment of level of pain among preterm infants undergoing painful procedure using the PIPP scale.
4. The nurse administrator should enforce in organizing Continuing Nursing Education (CNE), conferences and workshop on facilitated tucking on level of procedural pain in preterm infants and other potential benefits.
5. The nurse administrator can allot separate budget for in-service education to disseminate the research findings to all nurses at various affiliated institutions.

6.3.4 Nursing Research

1. The findings of the study can be disseminated to the nurses working in NICU and student nurses through various media.
2. The generalization of the study results can be made further replication of the study in various settings and larger population.
3. More research can be done on the other factors influencing pain in preterm infants.

6.4 RESEARCH DISSEMINATION

1. Research findings of the main study were presented in the 4th International conference held at Omayal Achi College of Nursing, 2016.
2. Research results will be published in the Online Journal of ICCR, www.iccrjnr.com.
3. Research findings will be put up in newspaper articles.

6.5 UTILIZATION OF RESEARCH FINDING

The research will be successfully implemented in Amma Hospital, Choolaimedu and Sir Ivan Stedeford Hospital, Ambattur, Chennai.

6.6 RECOMMENDATIONS

The researcher presents strong recommendation to the neonatal nurses, to involve actively in on prevention of the long-term consequences of repeated painful stimuli through the simple cost-effective nursing measure, facilitated tucking during the routine painful procedures.

The study recommends the following for further research.

1. The researcher will recommend the neonatal nursing staff to feed the preterm infants with breast milk before the painful procedure as it serves as natural analgesia.
2. The researcher will recommend to perform painful procures when the preterm infant is in quiet/ sleep state and avoid unnecessary manipulation of preterm infants before the painful procedure in order to reduce the perception of pain level.
3. The researcher will recommend for implementing the facilitated tucking in preterm infants undergoing painful procedure in the clinical area by the students of Omayal Achi College of Nursing and its affiliated Hospitals.
4. A comparative study can be conducted to compare the effectiveness of facilitated tucking with other non-pharmacological pain relief measures.
5. The study can be replicated with large samples in various other settings for reinforcement.
6. A study can be conducted to assess the effectiveness of facilitated tucking on various other growth parameters among preterm infants.

6.7 LIMITATIONS

1. The investigator found difficulty in getting setting permission and number of samples within the scheduled time.
2. The investigator had difficulty in getting related Indian literatures.

REFERENCES

REFERENCES

BOOKS:

Agarwal, L. (2006). *Modern Educational Research*. New Delhi: Dominant Publishers and distributors.

Alexander F., Josephine, M. F. N., et al., (2001). *Nursing Practice, Hospital and Home* second edition Spain: Churchil Livingstone – Har Court Publishers Limited.

Bala. (2007). Fundamentals of Biostatistics. New Delhi: Ane publications.

Basavanthappa, B.T. (2008). *Nursing Theories*. Bangalore: Jaypee brothers.

Betty, M Johnson., & Pamela, B webber. (2005). *An Introduction to Theory and Reasoning in nursing*. USA: Evolve Elsevier publication.

Behrman, Richard E. (1999). *Nelson's Textbook of Paediatrics*. Philadelphia: Saunders Company

Brian, Luke Seavard. (2009). *Managing Stress Principles and Strategies for Health and Wellbeing.* Philadelphia: Lippincott Company.

Datta, Parul. (2007). *Paediatric Nursing*. New Delhi. Jaypee Brothers Medical Publications.

Dipak, K Guha. (2005). *Guha's Neonatology: Principles and practices*. New Delhi. Jaypee Brothers Medical Publications.

Elizabeth ., & Hurlock. (1970). *Child Growth and Development*. New York: McGraw Hill.

Elzouki, Abdelaziz Y., & Harb, Harf A. (2001). *Textbook of clinical pediatrics.*Philadelphia: Wllteys Kulwer company.

Fawcett, Jacquelin. (1984). *Analysis and Evaluation of Conceptual Models of Nursing.* Philadelphia: T.A Davis Company.

Florence, Blake G., & Howell, Wright F. (1998). *Nursing care of Children*. Philadelphia: J.B.Lippincott Company.

Ghai, O. P. (1982). *Essential Paediatrics*. New Delhi: Interprint Publications. Medical publishers Ltd.

Hockenberry, Marilyn J., et al., (2010). Wong's *Essential of paediatric nursing.* Missouri: Mosby publications.

Jane, Ball & Ru C. Bindler. (2000). *Paediatric Nursing – care for children.* Philadelphia: Mosby publication.

Joyce, J Fitz Patrick., et al. (1983) *Conceptual models of nursing – Analysis and Application.* Marylant: Apprentice Hall publishers.

Kyle, Tyre. (2009). *Essential of paediatric nursing*. New Delhi: Wolters Kluwer India Private Ltd.

Kozier, Barbara., et al., (2000). *Fundamentals of nursing concepts and process*. New York. Addison Wesley.

Leslie, N. H. (1992). *Perspective of nursing theory.* Philadelphia: J. P Lippincott publisher.

Mahajan, B. K. (2005). *Methods in biostatistics*, New Delhi: Jaypee brother publishers.

Marlow, Dorthy. R. (2005). *Textbook of Paediatrics*. Philadelphia: Saunders company.

Nancy, Burns. (2009). *The practice of nursing research.* Missouri: Saunders publications.

Parthasarathy, A. (2009). *IAP Textbook of Pediatrics.* New Delhi: Jaypee Brothers Medical Publishers.

Polit, F. D. (2010). Nursing research – principles and methods. Philadelphia: Lippincott company.

Polit, F.D., & Hungler, P. B. (2011). *Nursing research and principles and methods*. J.B.Lippincott company.

Rao, S. (2006). *Introduction to biostatistics and research method.* New Delhi: Prentice Hall of India.

Rao, S., et al.,(1999). *An introduction to biostatistics*. Vellore: Presto Graphic Printers. Thompson, Dumont Eleaner. (1992). *Paediatric Nursing*. Philadelphia: W. B. Saunders Company.

Viswanathan. (1991). *Textbook of pediatrics*. Hyderabad: Orient Longman Limited.

Wattz, F. C. & Baureli, B. P. (1981). *Nursing Research Design, Statistics and components and Analysis* . Philadelphia: FA Davis company.

Waechter, Eyenia H. (1985). *Textbook of children*. Philadelphia: J.B.Lippincott Company.

Wesky, L Ruby. (1995). *Perspective of nursing theories and Models*. Pennsylvania: Spring House Corporation.

William, Hathway E. (1995). *Current pediatric diagnosis and treatment*. London: Prentice Hall International.

Wong, L. Donna. (2006). *Whaley and Wongs Nursing Care of Infants and Children.* Philadelphia: Mosby Company.

Wood, G. L. B., & Haber, J. (1990). *Nursing Research Methods, Critical Appraisal and Utilization.* Toronto: CV. Mosby Company.

ONLINE JOURNALS:

Al Hebabi, J. (2010). A Reliable Pain Assessment Tool for Clinical Assessment in the Neonatal Intensive Care Unit - Spence - *Journal of Obstetric, Gynecologic, & Neonatal Nursing* - Wiley Online Library.

Alencar M, Cruz RM, (2010). Assessing pain in preterm infants in the neonatal intensive care unit_ moving to a "brain-oriented" approach.

Axelin A, Salantera S, Lehtonen L. (2010) Facilitated tucking by parents' in pain management of preterm infants—a randomized crossover trial. Early Hum Dev. Apr;82(4):241-7.

Anand KJ,(2010) and the International Evidence-Based Group for Neonatal Pain. Consensus statement for the prevention and management of pain in the newborn. *Arch Pediatr Adolesc Med* ;155:173-180.

Bouza H. The impact of pain in the immature brain. *Journal of Maternal Fetal Neonatal Medicine*. 2010; 22(9): 722-732. PMid:19526425

Badr LK, Abdallah B, Hawari M, Sidani S, Kassar M, Nakad P, Breidi J. Determinants of premature infant pain responses to heel sticks. *Journal of Neonatology* Pediatr Nurse. 2010;36(3):129-36.

Campbell-Yeo M, Fernandes A, Johnston C. Procedural pain management for neonates using nonpharmacological strategies: part 2: mother-driven interventions. *The Journal of Pediatrics* Research. Advances in Neonatal Care. 2011;11(5):312-8.

Carbajal R, Rousset A, Danan C, et al (2010). Epidemiology and treatment of painful procedures in neonates in intensive care units. *JAMA: The Journal of the American Medical Association.2* 010; 300(1): 60-70. PMid:18594041

Corbo MG, Mansi G, Stagni A, et al. Nonnutritive sucking during heelstick procedures decreases behavioral distress in the newborn infant. *Biol Neonate.* 2012;49:162–167

Cássia, G. De, Luzia, M., Ii, C., Clínicas, H. De, Alegre, D. P., Group, N. Porto, U. (2014). Prevention and non-pharmacological management of pain in newborns, *68*(1), 123–127.

Cignacco, A. E. L., & Sellam, G. (2012). Oral Sucrose and " Facilitated Tucking " for Repeated Pain Relief in Preterms : A Randomized Controlled Trial, *129*(2), 1–10. http://doi.org/10.1542/peds.2011-1879

Cignacco E, Hamers JP, Stoffel L, Van Lingen RA, Gessler P, McDougall J, Nelle M. The efficacy of non pharmacological interventions in the management of procedural pain in preterm and term neonates. A systematic literature review. Eur J Pain. (2010) Feb;11(2): 139-52.

Continuing, E. B., & Resource, E. (n.d.). Assessment and management of acute pain in the newborn.

Fernandes A, Campbell-Yeo M, Johnston CC (2011). Procedural Pain Management for Neonates Using Nonpharmacological Strategies Part 1: Sensorial Interventions. *Adv Neonatal Care.* 2011;11:235–241.

Gallo, A. (2013). The Fifth Vital Sign : Implementation Nhttp://doi.org/10.1177/0884217503251745

Gibbins, S., & Nnp, R. N.(2010) . Pain Assessment and Management in pretem infants.

Holsti L, Oberlander TF, Brant R.(2012) *Does breastfeeding reduce acute procedural pain in preterm infants in the neonatal intensive care unit? A randomized clinical trial. . Pain.* 2011;152:2575–2581.

Johnston CC, Campbell-Yeo M, Filion F, (2014) Paternal vs maternal kangaroo care for procedural pain in preterm neonates: a randomized crossover trial. *Arch Pediatr Adolesc Med.* 2011;165:792–796.

Johnston CC, Filion F, Campbell-Yeo M, et al.(2010) Kangaroo mother care diminishes pain fromheel lance in very preterm neonates: a crossover trial. *BMC Pediatr*. 2010 ;8:13–22.

Kaur, M., Deol, R., Bains, H. S., & Kaur, J. (2014). Research article effect of facilitated tucking on level of heel lance procedural pain among preterm neonates. *The*

Journal of Child Neurology.

Kucukoglu, S., Kurt, S., & Aytekin, A. (2015). Of pediatrics The effect of the facilitated tucking position in reducing vaccination-induced pain in newborns. *Italian Journal of Pediatrics*,1–7. http://doi.org/10.1186/s13052-015-0168-9

Kumar, M. et al. (2010) Music for medical indications in the neonatal period: A systematic review of randomised controlled trials. *Archives of Disease in Childhood*, published online..

Liaw JJ, Yang L, Katherine Wang KW, Chen CM, Chang YC, Yin T. (2011) Non-nutritive sucking and facilitated tucking relieve preterm infant pain during heel-stick procedures: a prospective, randomised controlled crossovertrial *International Journal of Nursing Studies*.

Lopez O, Subramanian P, Rahmat N, Chin Theam L, Chinna K, Rosli R. (2012). The effect of facilitated tucking on procedural pain control among premature babies. *Journal of Clinical Nursing.*

Lowery, C. L., Hardman, M. P., Manning, N., Hall, R. W., & Anand, K. J. S. (2010). Neurodevelopmental Changes of Fetal Pain. *The Journal of Chil Neurology.* http://doi.org/10.1053/j

Lubetzky, R. et al. (2010).Effect of music by Mozart on energy expenditure in growing preterm infants. *The Journal of* Pediatrics*,* Vol. 125, January, pp. e24-8.

Manuscript, A. (2012). unit : moving to a " brain-oriented " approach, *1*(2), 171–179. http://doi.org/10.2217/pmt.10.19.

Mathew, P. J., & Mathew, J. L. (2010). Assessment and management of pain in infants, 438–443. the Journal of Child Health.

Midmer, D. K. (n.d.). iiX A Special Report Pain Perception in the Neonate : A Matter of Opinion, 1049–1054.

Reyes, S. (2011). Nursing assessment of infant pain. *Journal of Prenatal and Neonatal Nursing,* 17(4), 291-303. doi: 10.1542/peds.100.4.626

Riddell, R. P., Ma, N. R., Ba, K. T., Uman, L. S., Ma, R. H., Din, L.Turcotte, K. (2011). Nonpharmacological management of procedural pain in infants and young children : *The Jouranl of pediatrics.*

Rouzan, I. A. (2010). An analysis of research and clinical practice in neonatal pain

management. *Journal of the American Academy of Nurse Practitioners,* 13(2), 57-60. doi: 10.1111/j.1745-7599.2001.tb00218.x

Sellam, G. (2012). non - pharmacological pain relief interventions and contextual factors influencing pain response in preterm infants : are we measuring what we intend to measure ?. *The Indian journal of pediatrics.*

Stevens, B., Yamada, J., Beyene, J., Gibbins, S., Petryshen, P., Stinson, J., & Narciso, J. (2012). Consistent Management of Repeated Procedural Pain With Sucrose in Preterm Neonates : Is It Effective and Safe for Repeated Use Over Time ?, *21*(6), 543–548.

Standley J. Music therapy research in the NICU: an updated meta-analysis. Neonatal Netw.2012;31:311–316.

Sucrose for analgesia in newborn infants undergoing painful procedures - Cochrane Database of Systematic Reviews - Stevens - Wiley Online Library.

Sundaram B, Shrivastava S, Pandian JS, Singh VP (2010) Facilitated tucking on pain in pre-term newborns during neonatal intensive care: a single blinded randomized controlled cross-over pilot trial. Article first published online DOI: 10.1111/j.1552-6909.1995.tb02456.

Tayebe Reyhani ,Seyedeh Zahra Aemmi, Tahere Mohebbi , Hasan Boskabadi (2014) The Effect of Facilitated Tucking (FT) During Venipuncture on Duration of Crying in Preterm Infants. *International Journal of Pediatrics* , Vol.2, N.4-3, Serial No.12, December 2014

Vinall, J., & Grunau, R. E. (2014). Impact of repeated procedural pain-related stress in infants born very preterm, *75*(5), 584–587. http://doi.org/10.1038/pr.2014.16

Yamada J, Stinson J, Lamba J, Dickson A, McGrath PJ, Stevens B. (2010) A review of systematic reviews on pain interventions in hospitalized infants. *Pain Res Manag.* 2010;13:413–420.

WEBSITES:

http://dx.doi.org/10.5430/jnep.v3n8p99

http://dx.doi.org/10.3109/14767050902926962

http://dx.doi.org/10.1001/jama.300.1.60

http://dx.doi.org/10.1590/S0103-507X2011000300016
http://dx.doi.org/10.1542/peds.114.1.e77
http://dx.doi.org/10.1203/PDR.0b013e3181cb8e2f.
http://dx.doi.org/10.1002/ana.22267
http://dx.doi.org/10.1002/ana.22545.
http://dx.doi.org/10.1053/nbin.2001.25302
www.jneonatalsurg.com
www.qatar.ucalgary.ca/acwr/
www.hkjpaed.org/pdf/2013;18;19-23.pdf
www.emedicine.medscape.com
www.sciencedaily.com/releases/2012/07/120702152649.html.

PUBLISHED REPORTS:

World Health Organisation **(2012): Preterm Birth**

World Health Organisation **(2013) Born Too Soon: the Global Action Report on Preterm Birth**, in the year 2013.

International Association for the Study of Pain (2010): consequences of repeated painful stimulus in preterm neonates.

The International Evidenced Based Group for neonatal pain and the American Academy of Pediatrics (2010): Non-pharmacological pain relief measures in Neonatal Intensive Care Unit.

Global Report on Preterm birth and Still Birth (2010).

NEWS PAPER:

India shares highest preterm birth burden: Times of India- 07- June-2012.

Preterm birth is the No.1 cause for rise in Neonatal Mortality Rate:NPR- 17- November-2014

Why are so many new borns still being denied pain relief: Times of India- 04-February-2016.

APENDICES

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Run by MR Omayal Achi MR Arunachalam Trust

ETHICAL CLEARANCE CERTIFICATE

Valid from: December 2014
Valid to: May 2016

Name of the Principle Investigator: Ms. Rubin Selvarani.G, M.Sc. (N) Student (Child Health Nursing)

The **ICCR** Ethical Committee meeting held on 22.12.2014 had reviewed the project titled **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai."** The proposal was found to be acceptable on ethical grounds. The Principle Investigator has the responsibility and accountability for any other administrative / regulatory approvals that may pertain to this research project and for ensuring that the authorized research is carried out according to the conditions outlined in the original protocol submitted for ethics review.

This certificate of approval is valid for the time period provided, there is no change in the methodology protocol or consent process and documents.

Any significant change should be reported to Director for Research Committee considerations in advance for its implementation.

Signature of Research Director :

Signature of Researcher : Rubin Selvarani

45, AMBATTUR ROAD, PUZHAL, CHENNAI - 600 066. TAMIL NADU, INDIA
Tel : 26591617, 26591618, Fax : 26591616, E-mail : iccrphc@gmail.com, Website : www.omayaln.com

OMAYAL ACHI COLLEGE OF NURSING

Run by MR. Omayal Achi MR.Arunachalam Trust

45, AMBATTUR ROAD, PUZHAL, CHENNAI - 600 066.
(Affiliated to the Tamilnadu Dr.M.G.R. Medical University
Recognized by the Indian Nursing Council & TN Nurses and Midwives Council)

Love to Serve
அறஞ்செய விரும்பு

Tel : 26591617, 26591618
Fax : 26591616
E-mail : oacn1992@gmail.com
Website : omayaln.com

10.06.2015.

The Medical Director,
Amma Hospital,
7th Street,
Sowrashtra Nagar,
Choolaimedu,
Chennai-600 094.

Sir,

Sub: Request for permission to conduct
Research Study.

Ms.Rubin Selvarani.G, is a bonafide M.Sc(Nursing) I year student studying at our College and she is conducting "A STUDY TO ASSESS THE EFFECTIVENESS OF FACILITATED TUCKING ON LEVEL OF PAIN AMONG PRETERM INFANTS AT SELECTED SETTINGS, CHENNAI".

This is for her research project to be submitted to the Tamilnadu Dr.M.G.R. Medical University in partial fulfillment of the University requirement for the award of M.Sc(Nursing) Degree.

Further details of the proposed project will be furnished by the student personally. She will not hinder your routine in any way and she will abide by the rules and regulations of the Hospital. The information collected from your hospital will be kept confidential. I kindly request you to grant her permission to conduct the study at your Esteemed Hospital.

Thanking you,

Yours Sincerely,

OMAYAL ACHI COLLEGE OF NURSING

Principal

Dr. ANURADHA , MD(PAED)
Registered Medical Practi...
Regn. No: 48...

OMAYAL ACHI COLLEGE OF NURSING

Run by MR. Omayal Achi MR.Arunachalam Trust

45, AMBATTUR ROAD, PUZHAL, CHENNAI - 600 066.
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E-mail : oacn1992@gmail.com
Website : omayaln.com

Love to Serve
அறஞ்செய விரும்பு

10.06.2015.

The Medical Director,
Sir.Ivan Stedeford Hospital,
Ambattur,
Chennai-600 053.

Sir,

Sub: Request for permission to conduct
Research Study.

Ms.Rubin Selvarani.G, is a bonafide M.Sc(Nursing) I year student studying at our College and she is conducting "A STUDY TO ASSESS THE EFFECTIVENESS OF FACILITATED TUCKING ON LEVEL OF PAIN AMONG PRETERM INFANTS AT SELECTED SETTINGS, CHENNAI".

This is for her research project to be submitted to the Tamilnadu Dr.M.G.R. Medical University in partial fulfillment of the University requirement for the award of M.Sc(Nursing) Degree.

Further details of the proposed project will be furnished by the student personally. She will not hinder your routine in any way and she will abide by the rules and regulations of the Hospital. The information collected from your hospital will be kept confidential. I kindly request you to grant her permission to conduct the study at your Esteemed Hospital.

Thanking you,

Yours Sincerely,

OMAYAL ACHI COLLEGE OF NURSING
Principal

Permitted.

SIR IVAN STEDEFORD HOSPITAL
AMBATTUR
CHENNAI-53

REQUISITION LETTER FOR CONTENT VALIDITY

From

Ms. Rubin Selvarani.G,
M.sc (N) I year,
Omayal Achi College of Nursing,
No. 45, Ambattur road, Puzhal,
Chennai- 66.

To

Respected Madam,

Subject: Requisition for expert opinion for content validity.

I am Ms.Rubin Selvarani.G doing my M.sc Nursing I year specializing in Child Health Nursing at Omayal Achi College of Nursing under the guidance of Dr.Mrs.S Kanchana, Research Director, ICCR and Speciality Guide Ms.Ruthrani Princely.J, Head of the Department, Child Health Nursing. As a part of my research project to be submitted to the Tamil Nadu Dr. M.G.R. Medical University December 2014 session and in partial fulfillment of the University requirement for the award of M.Sc. (N) degree, I am conducting **"A study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected hospitals, Chennai".** I have enclosed my data collection and intervention tool for your expert guidance and validation.

Thanking you,

Yours faithfully,

(Ms. Rubin Selvarani.G)

ENCLOSURES:

1. Research proposal
2. Data collection tool
3. Intervention tool
4. Content validity form
5. Certificate for content validity

LIST OF EXPERTS FOR CONTENT VALIDITY

MEDICAL EXPERTS

1. **Dr. A.Anuradha.**
   MBBS, MD,
   Consultant Pediatrician and Neonatologist,
   Amma Hospital,
   No.1, Sowrastra Nagar, 7th street,
   Chooliamedu, Chennai – 600 094, Tamil Nadu.
2. **Dr. Jayasheela.K**
   MBBS, MD (Paed), DM (Neonatology),
   Neonatologist,
   Sir Ivan Stedeford Hospital,
   Ambattur, Chennai – 600 053, Tamil Nadu.

CHILD HEALTH NURSING EXPERTS

1. **Dr.A.Judie, M.Sc.,(N), ph.D.,**
   Dean, SRM College of Nursing,
   SRM University, SRM Nagar,
   Kattankulathur-603 203

2. **Mrs. Nesa Sathya Satchi, M.Sc (N).,**
   H.O.D, Child Health Nursing,
   Apollo College of Nursing,
   Ayanambakkam,
   Chennai – 600095.

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that the data collection and intervention tool developed by **Ms. Rubin Selvarani .G** M.Sc.(Nursing) I year student of Omayal Achi College of Nursing for her study **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai"** under the specialty guide **Mrs.Ruthrani Princely .J,** Head of the Department, Child Health Nursing, is validated by the undersigned and she can proceed with this tool to conduct the main study.

Dr. A. Anuradha

Signature with date:

Seal: Dr. ANURADHA , MD(PAED)
Registered Medical Practitioner
Regn. No: 48375

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that the data collection and intervention tool developed by **Ms. Rubin Selvarani .G** M.Sc.(Nursing) I year student of Omayal Achi College of Nursing for her study **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai"** under the specialty guide **Mrs.Ruthrani Princely .J,** Head of the Department, Child Health Nursing, is validated by the undersigned and she can proceed with this tool to conduct the main study.

14/8/15

Signature with date:

Dr. A. JUDIE, M.Sc., (N), Ph.D.,
Dean
SRM College of Nursing
SRM University, SRM Nagar,
Kattankulathur - 603 203,
Kancheepuram Dist., Tamil Nadu.

Seal:

CERTIFICATE FOR CONTENT VALIDITY

This is to certify that the data collection and intervention tool developed by **Ms. Rubin Selvarani .G** M.Sc.(Nursing) I year student of Omayal Achi College of Nursing for her study **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai"** under the specialty guide **Mrs.Ruthrani Princely .J,** Head of the Department, Child Health Nursing, is validated by the undersigned and she can proceed with this tool to conduct the main study.

Signature with date: 12/05/15

(NESA SATHYA SAICHI)

Seal:

APPENDIX – D

NO HARM CERTIFICATE FOR THE INTERVENTION

Name of the investigator : Ms. Rubin Selvarani.G

Name of the intervention : Facilitated tucking.

Indicated client group : Preterm infants.

Method : One-to-one.

Venue : Neonatal Intensive Care Unit (NICU).

Indications : Routine painful procedure (Heel prick, intramuscular injections, blood sample collection, venipunctures, lumbar puncture, endotracheal suctioning).

Contraindication : Clinically unstable preterm infants.

Preliminary measures :

Steps	Nursing actions
1.	Select the preterm infant based on the inclusion and exclusion criteria
2.	Assess the demographic variables of the preterm infant.
3.	Observe the physiological and behavioral parameters of the preterm infant for duration of 15 seconds
4.	Manually record the physiological parameter from calibrated pulse oxymeter (maximum heart rate and minimum oxygen saturation levels)
5.	Record the behavioral parameters such as eye squeeze, brow bulge and nasolabial furrow by video clipping simultaneously for 15 seconds.

Steps of intervention:

Steps	Nursing actions
1.	Perform thorough hand hygiene to prevent the spread of cross infection.
2.	Dry hands with sterile towel or tissue paper.
3.	Wear personal protective equipment such as apron, face mask and cap as aseptic precautionary measures.
4.	Warm the hands by rubbing palm against palm to provide warmth touch to

	the preterm infant.
5. **6.**	Using sense of touch gently turn the preterm infant to the lateral position. Gently flex the arms and legs to the midline of the trunk stimulating a condition of being in uterus resulting in controlled response to pain.
7.	Retain the tucked position on the preterm infant throughout the painful procedure to maintain the self- regulated response to painful stimulus.

After the procedure **:** After the event of painful procedure on tucked preterm infant;

Steps	**Nursing actions**
1.	Observe the physiological and behavioral parameters of the preterm infant for duration of 30 seconds.
2.	Manually record the physiological parameter from calibrated pulse oxymeter (maximum heart rate and minimum oxygen saturation levels).
3.	Record the behavioral parameters such as eye squeeze, brow bulge and nasolabial furrow by video clipping simultaneously for the same duration of 30 second.

When to stop the intervention **:** As the preterm infant becomes comfortable (returns back to baseline physiological state and without any expressions of pain such as eye squeeze, brow bulge and nasolabial furrow) un-tuck the infant and place them in pre-procedural position.

Preterm infants undergoing routine painful procedure at NICU will be given the simple, cost-effective, non-pharmacological nursing measure facilitated tucking that reduces the level of pain during painful procedure. The above mentioned intervention is safe, secure and will not harm the preterm infants. The video clippings recorded during the painful procedures are only to interpret the pain level with the use of standardized tool known as Premature Infant Pain Profile (PIPP) scale and I assure that the video recordings will not be misused or harm the preterm infant at any cost

Signature: **Seal:**

APENDIX-E

CERTIFICATE OF ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that MsRubin Selvarani.g, M.Sc nursing II year student of Omayal Achi College of nursing Chennai, conducted a dissertation work on **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected hospitals, Chennai. 2015"** under the guidance of Mrs. Ruthrani Princely.J, as a partial fulfillment of The Tamil Nadu Dr. M.G.R medical university requirement for the award of M.Sc Nursing degree is edited for English language appropriateness by_____

Seal: Signature with Date

APPENDIX – E

CERTIFICATE OF ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms.G.Rubin Selvarani M.Sc Nursing II year student of Omayal Achi College of nursing Chennai, conducted a dissertation work on **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected hospitals, Chennai. 2015"** under the guidance of Mrs. Ruthrani Princely.J, as a partial fulfillment of The Tamil Nadu Dr. M.G.R Medical University requirement for the award of M.Sc Nursing degree is edited for English language appropriateness by MARIA JOSEPH. I

Seal:

Signature with Date 27/4/15

I. MARIA JOSEPH M.A.,M.A.,M.Ed.,M.Phil.,
Graduate Teacher (B.T. Asst.)
Govt. Panchayat Union Middle School,
Kuthampoondi, Vikravandi Taluk,
Villupuram District - 605 652.

APENDIX-F

CERTIFICATE OF TAMIL EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that MsRubin Selvarani.g, M.Sc nursing II year student of Omayal Achi College of nursing Chennai, conducted a dissertation work on **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected hospitals, Chennai. 2015"** under the guidance of Mrs. Ruthrani Princely.J, as a partial fulfillment of The Tamil Nadu Dr. M.G.R medical university requirement for the award of M.Sc Nursing degree is edited for tamil language appropriateness by_____

Seal: Signature with Date

CERTIFICATE OF TAMIL EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ms.G.Rubin Selvarani M.Sc Nursing II year student of Omayal Achi College of nursing Chennai, conducted a dissertation work on **"A quasi experimental study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected hospitals, Chennai. 2015"** under the guidance of Mrs. Ruthrani Princely.J, as a partial fulfillment of The Tamil Nadu Dr. M.G.R Medical University requirement for the award of M.Sc Nursing degree is edited for Tamil language appropriateness by A·NATARAJAN

Seal:

A. NATARAJAN, M.A.,B.Ed.
B.T. TEACHER, (T)
P.U.M. SCHOOL, KUTHAMPOONDI,
VIKRAVANDI BLOCK,
VILLUPURAM DISTRICT. 605 652

Signature with Date 27/4/15

APPENDIX – G

INFORMED CONSENT REQUISITION FORM

From

Ms. Rubin Selvarani.G,
M.sc (N) I year,
Omayal Achi College of Nursing,
No. 45, Ambattur road, Puzhal,
Chennai- 66.

To
The Parent/Guardian of _____
ID.NO _____
Neonatal Intensive Care Unit.

Good Morning,

I Ms.Rubin Selvarani.G, M.sc, (Nursing) student from Omayal Achi College of Nursing, Chennai, conducting **"a study to assess the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedure at selected Hospitals, Chennai,"** as a partial fulfilment of the requirement for the degree of M.Sc. Nursing under The Tamil Nadu Dr. M.G.R. Medical University.

I assure you that information provided by you will be kept confidential and the video recordings of the facial expressions of your child will be used only to interpret the level of pain . So, I request you to kindly cooperate with me and participate in this study by giving your frank and honest responses to the questions being asked.

Thank you.

Signature of the investigator
Ms.Rubin Selvarani.G

INFORMED WRITTEN CONSENT FORM

I father or mother of _____aged _____ understand that my child (younger than 18 years of age) being asked to participate in a research study conducted by Ms.Rubin Selvarani.G, M.Sc nursing student of Omayal Achi College of Nursing Puzhal. This research study will evaluate **"the effectiveness of facilitated tucking on level of pain among preterm infants undergoing painful procedures at selected Hospitals, Chennai".** If I agree to participate my child in the study, I will be given structured questionnaire to know the demographic variable and my child will be observed by a video record during the painful procedure for the level of pain by use of Premature Infant Pain Profile (PIPP) Scale. The data will be kept confidential. No identifying information will be included during the analysis process. I understand that there are no risks associated with this study.

I realize that the knowledge gained from this study may help either my child or other children in the future. I realize that my child's participation in this study is entirely voluntary and I may withdraw my child from the study at any time I wish. If I decide to discontinue my child's participation in this study, my child will be continued to be treated in the usual and customary fashion.

I understand that all study will be kept confidential. However, this information may be used in nursing publication or presentations. If I need to, I can contact Ms. Rubin Selvarani.G, M.sc Nursing 1st year Omayal Achi College of Nursing Puzhal, phone no: 04426501617 at any time during the study. The study has been explained to me. I have read and understood the consent form, my entire question has been answered, and I agree to participate my child in the study. I understand that I will be given a copy of this signed consent form.

---------- ----------

Thumb print/Signature of parent Date:

---------- ----------

Signature of investigator Date

முன் அறிவிப்பு ஒப்ந்த படிவம்

உமையாள் ஆச்சி செவிலியர் கல்லுரியின் சார்பில் முதுநிலை பட்டப்படிப்பு முதாலம் ஆண்டு பயிலும் செல்வி. ரூபின் செல்வராணி அவர்களால் நடத்தப்படும் இந்த ஆய்வில் நான் _____ தாய்/தந்தை _____ வயது உள்ள எனது குழந்தையை பங்கேற்கக் கேட்டுக்கொண்டதை ஏற்றுக்கொள்கிறேன். இந்த ஆராய்ச்சியானது பச்சிளம் குழந்தை, தீவிர சிகிச்சைப் பிரிவில், குறைமாதத்தில் பிரசவித்த எனது குழந்தைக்கு குறிப்பிட்ட சில மருத்துவ சிகிச்சையின் போது ஏற்படக்கூடிய வலியைக் கட்டுப்படுத்த ஒரு எளிய வழிமுறையைப் பற்றிய ஆய்வாகும்.

இந்த ஆய்வுக்கு நான் எனது குழந்தையின் பங்களிப்பை ஒப்புக் கொண்டால், என்னிடம் கேட்க்கப்படும் அனைத்துக் கேள்விகளும் மற்றும் எனது குழந்தையின் வலியின் அளவினைக் கண்டறிய, பதிவு செய்யப்படும் வீடியோ பதிவுகளும் இந்த ஆய்வுக்காக மட்டுமே பயன்படுத்தப்படும் என்பதையும், இந்த எளிய வழிமுறையானது குறிப்பிட்ட சில மருத்துவ சிகிச்சையின் போது ஏற்படக்கூடிய வலியைக் கட்டுப்படுத்துவது மட்டுமல்லாமல் அவ்வலியினால் ஏற்படக்கூடிய பின்விளைவுகளையும் தடுக்கலாம் என்றும், இதன் மூலம் எனது குழந்தைக்கு எந்த பாதிப்பும் இல்லை என்பதயும் அறிவேன். இந்த ஆய்விலிருந்து நான் விலகிக் கொள்ளவும் எனக்கு முழு உரிமை உண்டு என்பதையும் அறிவேன். அவ்வாறு இவ்ஆய்விலிருந்து விலகிக் கொள்ளும் பட்ச்சத்தில் என் குழந்தைக்கு மற்ற குழந்தைகள் போலவே சிகிச்சை வழங்கப்படும் என்றும் நான் அறிவேன்.

என் குழந்தையைப் பற்றிய அனைத்து தகவல்களும் இரகசியமாகப் பாதுகாக்கப்படும் என்பதையம் தேவைப்படும் போது ஆய்வின் முடிவுகள் மற்றும் புகைப்படங்களை செவிலியர் சார்ந்த பத்திரிக்கைகளிலும் வெளியிட எனது முழு சம்மதத்தையும் அளிக்கிறேன். இந்த ஆய்வில் தேவைப்படும்போது எப்பொழுது வேண்டுமானாலும் செல்வி.ரூபின் செல்வராணி அவர்களையோ அல்லது உமையாள் ஆச்சி செவிலியர் கல்லுரியியைத் தொடர்புக் கொள்ளலாம் என்பதயும் நான் நன்கு அறிவேன்.

இந்த ஆய்வு பற்றிய முழு விளக்கமும் எனக்கு தெரிவிகப்பட்டது. இந்த ஆய்வுக்குத் தேவையான கேள்விகளுக்கு தகுந்த பதில்களை அளித்து முழு மனதுடன் எனது குறைமாத்தில் பிரசவித்த குழந்தையை பங்குகொள்ள சம்மதம் அளிக்கிறேன். இந்த ஒப்பந்த படிவத்தின் நகல் எனக்கு அளிக்கப்படும் என்றும் அறிவேன்.

பெற்றோரின் கையொப்பம் / கைரேகை தேதி:

ஆராய்ச்சியாளரின் கையொப்பம் தேதி:

ஒப்புதல் படிவம்

வணக்கம்,

செல்வி. ரூபின் செல்வராணி ஆகிய நான் புழலில் உள்ள உமையாள் ஆச்சி செவிலியர் கல்லூரியல் முதுநிலைப் பட்டப்படிப்பு முதலாம் ஆண்டு பயின்று வருகிறேன். என் படிப்பின் ஒரு பகுதியாக "பச்சிளம் குழந்தை தீவிர சிகிச்சைப் பிரிவில், குறைமாதத்தில் பிரசவித்த குழந்தைக்கு, குறிப்பிட்ட சில மருத்துவ சிகிச்சையின் போது ஏற்படக்கூடிய வலியைக் கட்டுப்படுத்த ஒரு எளிய வழிமுறை" பற்றிய ஆய்வை மேற்கொண்டுள்ளேன்.

தங்களிடம் சேகரிக்கப்படும் அனைத்து தகவல்களும் இரகசியமகப் பாதுகாக்கப்படும் என்பதையும் மற்றும் தங்கள் குழந்தையின் வலியின் அளவினைக் கண்டறிய, பதிவு செய்யப்படும் வீடியோ பதிவுகளும் இந்த ஆய்வுக்காக மட்டுமே பயன்படுத்தப்படும் என்பதையும் தெரிவித்துக் கொள்கிறேன். எனது இந்த ஆய்வுக்கு தங்களது முழு ஒத்துழைப்பையும் தருமாறு வேண்டிக்கேட்டு கொள்கிறேன்.

நன்றி

APPENDIX – H

RESEARCH TOOL

PART-1 DEMOGRAPHIC DATA

Instructions: Choose appropriate option

1. Gestational age in weeks

   A. 26
   B. 27
   C. 28
   D. 29
   E. 30
   F. 31
   G. 32
   H. 33
   I. 34
   J. 35
   K. 36

2 Gender

   A. Male
   B. Female

3 Weight in grams

   A. < 1500 g
   B. 1500 -2000 g
   C. 2000 -2500g

4. APGAR score at 5 th minute

   A. 5-7
   B. > 7

5. Type of feed before painful procedure

   A. Breastfeed
   B. Formula feed
   C. Breastfeed and formula feed
   D. Others

6. Mode of feed

   A. Oral feeds
   B. Nasogastric tube feed
   C. Parenteral feed

7. Time of last feed

   A. Less than 15 minutes.
   B. 15 minutes -30 minutes before
   C. 30 minutes - 1 hour before
   D. More than 1 hour before

8. Drug prescribed for the preterm infant

   A. Analgesics
   B. Antibiotic
   C. Sedative
   D. Others
   E. Combination of drugs specify_____

9. Time of last drug administration

   A. Less than 15 minutes.
   B. 15 minutes -30 minutes before
   C. 30 minutes - 1 hour before
   D. More than 1 hour before

10. Size of the needle

A. 28 gauge

B. 26 gauge

C. 24 gauge

11. Duration of the Procedure

A. < 1 minute

B. 1- 2 minute

C. 2-3 minutes

D. > 3 minutes

12. Length of hospitalization

A. Newly admitted

B. 1-3 days

C. 4-6 days

D. < 6 days

13. External stimulus before the painful procedure.

A. Present

B. Absent

PART – II

Premature Infant Pain Profile (PIPP) Scale

Process	Indicator	0	1	2	3
	Gestational Age	36 weeks and more	32 – 35 weeks, 6 days	28- 31 weeks, 6 days	27 weeks and less
	Behavioral State	Quite\ Sleep Eyes closed no facial movements	Quiet \Awake Eyes open No Facial Movements	Active\Sleep Eyes Closed Facial Movements	Active\Awake Eyes open Facial Movements
Observe infant for 30 sec	**Heart Rate**	0-4 beats/min Increase	5-14 beats/min Increase	15-24 beats/min Increase	25 beats/min or more Increase
	Oxygen Saturation	92-100 %	89-91%	85-88%	84% or less
	Brow Bulge	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more
	Eye Squeeze	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more
	Nasolabial Furrow	None 0-9% of time	Minimum 10-39% of time	Moderate 40-69% of time	Maximum 70% of time or more
				TOTAL SCORE	

Scoring key

Score	Interpretation
0-5	Generally indicates the infant has Minimal or No Pain
6-10	Generally indicates slight to Moderate Pain
>10	May indicate Severe Pain

APPENDIX – I

CODING FOR THE DEMOGRAPHIC VARIABLES

Demographic Variables No.	Code
1. Gestational age in weeks	
A. 26	1
B. 27	2
C. 28	3
D. 29	4
E. 30	5
F. 31	6
G. 32	7
H. 33	8
I. 34	9
J. 35	10
K. 36	11
2. Gender	
A. Male	1
B. Female	2
3. Weight in grams	
A. < 1500	1
B. 1500 -2000	2
C. 2000 -2500	3
4. APGAR score at 5 th minute	
A. 5-7	1
B. > 7	2

5. Type of feed before painful procedure
    A. Breastfeed 1
    B. Formula feed 2
    C. Breast feed and formula feed 3
    D. Others 4

6. Mode of feed
    A. Oral feeds 1
    B. Nasogastric tube feed 2
    C. Parenteral feed 3

7. Time of last feed
    A. Less than 15 minutes. 1
    B. 15 minutes -30 minutes before 2
    C. 30 minutes – 1 hour before 3
    D. More than 1 hour before 4

8. Drug prescribed for the preterm infant
    A. Analgesics 1
    B. Antibiotic 2
    C. Sedative 3
    D. Others 4
    E. Combination of drugs specify_____ 5

9. Time of last drug administration
    A. Less than 15 minutes. 1
    B. 15 minutes -30 minutes before 2
    C. 30 minutes - 1 hour before 3
    D. More than 1 hour before

10. Size of the needle

A. 28 gauge	1
B. 26 gauge	2
C. 24 gauge	3

11. Duration of the Procedure

A. < 1 minute	1
B. 1- 2 minute	2
C. 2-3 minutes	3
D. > 3 minutes	4

12. Length of hospitalization

A. Newly admitted	1
B. 1-3 days	2
C. 4-6 days	3
D. < 6 days	4

13. External stimulus before the painful procedure.

A. Present	1
B. Absent	2

APPENDIX-J

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S.No	Content	Item	Total item	Percentage
1.	Demographic variables	1-13	13	100%
2.	**PIPP scale** Gestational age	0-3	4	14.28%
	Sleep /awake state	0-3	4	14.28%
	i) Physiological indicator: Heart rate	0-3	4	14.28%
	Oxygen saturation	0-3	4	14.28%
	ii) Behavioural indicator: Brow bulge	0-3	4	14.28%
	Eye squeeze	0-3	4	14.28%
	Nasolabial furrow	0-3	4	14.28%
	Total	**28**	**28**	**100%**

APPENDIX- K

INTERVENTION TOOL

FACILITATED TUCKING:

Facilitated Tucking is one of the simplest non-pharmacological and cost effective techniques simulating the condition of being in uterus. This makes the infant comfortable, more secure with controlled response. It facilitates self-regulation by decreasing the physiologic response like prolonged heart rate elevation that contributes to the disequilibrium associated with pain and stress. Facilitated Tucking improves the emotional security and reduces the pain perception.

Pre-procedure:

The investigator performed the intervention for those selected infants undergoing painful procedure. The demographic variables were assessed from the medical records and the hemodynamic status such as maximum heart rate and minimum oxygen saturation level of the preterm infants using calibrated pulse oxymeter as the base line physiological indicator for duration of 15 seconds.

During the procedure:

The investigator performed thorough hand hygiene and wore on a sterile apron, cap and face mask as an aseptic precautionary measures. The investigator performed warming of hands by rubbing the palm against palm to provide a sense of touch on the preterm infant, gently turned the infant to the lateral side and positioned the arms and legs flexed, to the middle of the trunk. The neonatal nursing staff performs the heel prick procedure.

After the procedure:

The investigator retained the facilitated tucking position of the preterm infant after the painful procedure and assessed the physiological indicators such as heart rate and oxygen saturation levels by the calibrated pulse oxymeter for duration of 30 seconds whereas the behavioural indicators such as asleep/ wake state, brow bulge, nasolabial

furrow, eye squeeze were video recorded by the co-staff nurse for the same duration of 30 seconds simultaneously after the painful procedure.

As the preterm infant becomes comfortable (returns back to baseline physiological state and without any expressions of pain such as eye squeeze, brow bulge and nasolabial furrow)
un-tuck the infant and place them in pre-procedural position.

Interpretation:

The level of pain was assessed by PIPP Scale for both the groups. Preliminary observation was made and gestational age of the preterm infant was identified from the medical record. Preterm infants with the gestational age of 36 were scored with the pain score of 0, whose gestational age was between 32-35 were scored with pain score of 1, preterm infants with the gestational age of 28-3 were scored with the pain score of 2 and those who were below 27 weeks of gestation were scored with the pain score of 3. Physiological indicator of the preterm infant such as maximum heart rate and the minimum oxygen saturation level assessed after the painful procedure for duration of 30 seconds was compared with the maximum heart rate and the minimum oxygen saturation level which was recorded for duration of 15 seconds before the painful procedure to determine the number of increased beats in heart rate and decrease in level of oxygen saturation.

Preterm infants who had 0-4 beats increase in 30 seconds was scored as 0; who had 5-14 beats increase in 30 seconds was scored as 1; who had 15-24 beats increase in 30 seconds were scored as 2 and who had 25 beats increase and more were scored with the pain score of 3. In the same way preterm infants whose oxygen saturation level were in the range of 92-100% was given the score of 0, who were in the range of 89-91% was scored as 1, who were in the range of 85-88% was scored as 2 and who were with decreased saturation level of 84% and less was scored with the pain score of 3.

The behavioural indicators was interpreted by the facial expressions of the preterm infants which was video recorded for 30 seconds after the painful procedure. The 30 second video of each sample was played for three consecutive times to determine the

duration of each facial expression such as brow bulge, eye squeeze and nasolabial furrow.

The percentage of the facial expression was calculated by the following formula

$$\text{Time of facial expression in percentage} = \frac{\text{Duration of the single expression}}{\text{(Standard duration of observation as per PIPP scale)}} \times 100$$

The preterm infants who exhibited expressions for 0-9% were scored as 0, who exhibited expression for 10-39% were scored as 1, who exhibited 40-69% of expressions were scored as 2 and who expressed for 70% and more were scored with the pain score of 3. Cumulative scores of both physical and behavioural indicators were summed up and total pain score was derived.

The total pain score of preterm infants was interpreted as below:

0-5 - No pain or Mild pain

6-11 - Moderate pain

> 10 - Severe pain.

APPENDIX-L

PROTOCOL ON FACILITATED TUCKING

Definition:

Facilitated tucking is one of the simplest, safe, non-pharmacological and cost effective technique, where the preterm infants are positioned laterally with their arms flexed to the midline of the trunk that simulates the condition of being in uterus.

Indications:

Facilitated tucking can be given to preterm and term infants undergoing routine painful procedures such as;

- Blood sample collection
- Intramuscular injection
- Heel prick test
- Venepuncture
- Vaccination
- Endotracheal suctioning
- Lumbar puncture

Purpose:

- It makes the preterm infant feel more comfortable and secured during the painful procedures.
- It facilitates the preterm infants to control their response to painful stimulus by mechanism of self-regulation.
- It improves the emotional security and reduces the pain perception during painful events.

General instructions:

- Preterm infants experience pain from noxious stimuli and hence pain relief measure should be used to control pain during routinely performed painful procedures to prevent long term complications.

- Facilitated tucking should be performed using gentle sense of touch using pre-warmed hands to reduce the risk of hypothermia.
- Minimal pressure to be used to flex the arms and legs to midline of the trunk to avoid harm to the bony prominence.
- Care to be taken to avoid applying pressure over the invasive lines such as venipuncture sites and kinking of the IV tubing to avoid restricting the flow of fluid.

Steps of intervention:

Steps	Nursing actions	Rationale
1.	Perform thorough hand hygiene to	Prevents the spread of cross infection.
2.	Dry hands with sterile towel or tissue paper.	Maintains sterility of hands
3.	Wear personal protective equipment such as apron, face mask and cap.	Promotes aseptic precautionary measures.
4.	Warm the hands by rubbing palm against palm.	Ensures warmth and sense of touch to the preterm infant.
5.	Using sense of touch gently turn the preterm infant to the lateral position.	Soothes the preterm infant and reduces pain perception.
6.	Gently flex the arms and legs to the midline of the trunk.	Stimulates the condition of being in uterus resulting in controlled response to pain.
7.	Retain the tucked position on the preterm infant throughout the painful procedure.	Maintains the self- regulated response to painful stimulus.

After care :

As the preterm infant becomes comfortable un-tuck the infant and place them in pre-procedural position.

APENDIX-O

PHOTOGRAPHS

Investigator performed hand hygiene

Investigator wore on sterile apron, cap.

***Investigator wore on mask as aseptic precautionary measures*.**

Investigator recorded the baseline physiological indicator

before the intervention.

Investigator performed warming of hands to provide sense of touch on the preterm infant

Investigator gently turned the preterm infant to lateral position.

Investigator performed facilitated tucking by flexing the arms and legs flexed to the midline of the trunk.

Investigator assessed the physiological indicator

after the painful procedure.

Informed consent was obtained to publish the photographs in the dissertation.